Overcoming the Barriers to Adoption of Diagnostic Point-of-Care Testing (POCT) Technologies within Secondary Care

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Abstract

This thesis presents the findings from a detailed study of possible barriers to adoption of Point-of-Care Testing (POCT) within hospital-based healthcare. The issues concerned have been identified and categorised from a systematic review of the published literature over the period 2000-2016. The opinions of clinicians working in the UK have been obtained via face-to-face interviews and an online survey tool using semi-quantitative techniques by way of subsequent analysis. These data have then been compared with the outcomes from interviews with those employed in the US healthcare system. Based on these findings, a more targeted appraisal of the opinions of international Clinical Bioscientists was then undertaken. Overall, the central aim of the work was to categorise and better understand the core issues that have been identified as impeding the clinical uptake of POCT in both the UK and internationally. Importantly, the focus of the work was on how the most significant barriers can be overcome based on this new understanding of the circumstances.

There is a clear disconnect between the opinions of those responsible for operating POCT and those responsible for test data quality assurance, i.e. the Clinical Bioscientists, regardless of location. In particular, it was found that this relates mostly to specific quality-related issues, including the complexity of regulatory requirements and control of diagnostic testing. While economic issues were generally found to impact most significantly upon POCT adoption, it is indicated that the role of the medical insurer within the US healthcare system acts as an additional hurdle as compared to the situation in the UK (NHS).

Based on the research findings described herein a number of recommendations are made for overcoming the various barriers to POCT adoption in hospital-based healthcare, including; development of a sufficient evidence base for the clinical/economic benefits; development of regional procurement strategies; improved connectivity to the patient record systems; improved training processes; increased central laboratory service support, and; improved quality assurance processes.

Abbreviations

POCT	Point-of-Care Testing
CLT	Central Laboratory Testing
TAT	Turnaround Time
IT	Information Technology
ED/R	Emergency Department/Room
ACS	Acute Coronary Syndrome
NHS	National Health Service
INR	International Normalised Ratio
NPT	Near Patient Testing
PDA	Personal Digital Assistant
DRG	Diagnostic Related Group
FDA	Food and Drug Administration
CLIA	Clinical Laboratory Improvement Amendments
CPA	Chemical Pathology Accreditation
UKAS	United Kingdom Accreditation Service
NIH	National Institute of Health
NICE	National Institute of Clinical Excellence
HSCNI	Health and Social Care Northern Ireland
CRP	C-reactive Protein
NGAL	Neutrophil Gelatinase-Associated Lipocalin
ROM	Rupture of Membrane
UMass	University of Massachusetts
ICU	Intensive Care Unit
CE	Conformité Européenne (European Conformity)
GDP	Gross Domestic Product

Note on Access to Contents

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Chapter 1

Introduction to the Research

1.1 History of Modern Diagnostic Testing

The examination and analysis of a range of bodily fluids has long been recognised as being a critical step in the successful diagnosis and management of various medical conditions. Over the last century, the focus and approach to diagnostic testing has shifted dramatically with respect to benefits that have been gained from a range of fundamental scientific and technological developments, moving it from a basic physical assessment of bodily fluids towards a more detailed evaluation of their biochemical composition and the quantification of specific biomarkers related to pathology.

In historical terms, urine has been used for analytical purposes in the diagnosis of certain medical conditions due to its ease of acquisition, ready availability and relative abundance (Bolodeoku, Olukoga et al. 1998). The practice of visually examining a patient's urine for blood or other symptoms of disease is referred to as uroscopy and was considered routine practice as long ago as the late medieval period. It was then scientific breakthroughs such as the development of the microscope and the discovery of the complex constituents of blood laid the foundations for modern diagnostic tools and tests.

During the 18th century, medicine advanced significantly with the creation of textbooks categorising many new forms of disease and the introduction of drugs such as digitalis and opium. Furthermore, it was during this period that fundamental developments were established with regard to how examination of body temperature, pulse rate and blood pressure could be used for the deduction of a successful diagnosis. More sophisticated diagnostic techniques came to the fore in the 19th century, coinciding with the political, industrial and philosophical revolutions that were occurring on a global scale at that time (Berger 1999a). Medical practice developed at a rapid rate during the 1800's and so the provision of clinical diagnosis and disease management shifted from a primarily home bedside-based activity to that of hospital-based care where the more novel technologies and innovative techniques were accessible to a wider range of the population.

The development and progressive introduction of further laboratory tests to diagnose an increasing catalogue of diseases meant that dedicated clinical laboratories began to emerge as permanent fixtures of hospitals and other related healthcare facilities by the beginning of the

20th century. Interest in the detailed chemical evaluation of blood during this period can be correlated with the introduction of the hypodermic needle into widespread clinical practice (Bolodeoku, Olukoga et al. 1998). Likewise, microbiology and clinical chemistry developed into commonly recognised areas of medical specialist activity. Furthermore, blood banking for transfusions that were necessary during complex surgical procedures was introduced in the early part of the 20th century and this in turn necessitated blood grouping and basic functional testing (Berger 1999b). The introduction of clinical biochemistry as a specialism into the hospital laboratory setting, rather than relying solely on general physicians to undertake increasingly complicated testing, was recognition of both the success of the laboratory service and the need to ensure appropriate levels of quality assurance in the undertaking of such tests via provision of the requisite skills and dedicated expertise. This subsequently led to a career path for the training and certification of dedicated laboratory technicians, biomedical scientists and related specialisms.

1.2 Adoption of Centralised Analytical Testing

The mid-20th century onwards saw diagnostic testing of blood samples begin to be utilised on a much larger scale globally. Blood remains the most investigated bodily fluid in terms of biochemical and other forms of assessment. As the use of such tests increased, dedicated rooms (i.e. laboratories) became commonplace within hospitals equipped with the resources necessary for methods required to carry out the tests. This was a reflection of the fact that chemicals (quite often too hazardous for general purpose use) and particular (dedicated) pieces of equipment were now essential to deliver the required analytical service (Huckle 2008).

As the demonstrably positive effects of accurate laboratory based diagnostic testing were established clinically, this then led to an increasing volume of test requests being made by physicians within hospitals and other healthcare settings. This resulted in a number of laboratory tests and procedures (e.g. blood picture tests) emerging as routine components in the assessment of a patient's condition (Kotlarz 1998). As the underpinning technology continued to develop the associated analysis became increasingly more sophisticated and the value of precision in the diagnostic process began to be recognised as being of the upmost importance.

It has been suggested that 3 fundamental factors contributed to this adoption of centralised testing within hospitals and the development of the clinical laboratory service (Moore 2005). Firstly, the emergence of technology that allowed for more sophisticated analysis of specimens was an obvious driving force, particularly with regard to the benefits for more effective management of patients with less common medical conditions and diseases. Secondly, an

increasing requirement for appropriate logistics to co-ordinate testing led to the further embedding of an adequately resourced central laboratory service within hospitals that could meet the needs of both the patient and physician in terms of speed of access and convenience. This requirement incorporated efficiencies in the collection and preservation of samples, testing of specimens and the reporting of test results in a structured and organised manner. The notion of a centralised diagnostic testing service within a dedicated laboratory was deemed to be the most effective way to meet these requirements effectively. Thirdly, the economics of funding the costs of this increased testing followed on subsequently from the other logistical considerations with an increasing need for a laboratory-based testing service capable of delivering diagnostic tests at higher volume in an economically-viable and sustainable way. Only by concentration of test volumes within a dedicated laboratory service would it be possible to provide the economy of scale required to achieve this latter requirement.

The introduction of quality assurance schemes was a natural extension of the growth in diagnostic testing during the 20th century and directly aided the elimination of both variable and non-variable factors that had hitherto affected the value of the data provided by such tests (Bolodeoku, Olukoga et al. 1998). This significantly enhanced the quality of the data provided by the central laboratory service and added real clinical value in a way that was recognised as being of high importance. The tightly controlled confines of a dedicated laboratory and the provision of centralised quality assured testing systems and methods were seen as being highly favourable in terms of achieving consistent levels of reproducibility and repeatability in test outcomes and thereby increased their uptake significantly.

1.3 The Need for Faster Results: Turnaround Time (TAT)

The ever-increasing volume of diagnostic tests undertaken within hospitals has meant that the clinical laboratory service has continuously been required to adopt advances in technology in order to maintain service levels. Such adoption issues include the use of modern equipment, automated specimen processing, computerised reporting of results and more efficient specimen transportation systems (Steindel, Howanitz 2001). Despite this requirement, research has indicated that, in recent decades, laboratories have often found it difficult to meet the internally set goals for test turnaround time (TAT) (Hilborne, Oye et al. 1989, Steindel, Howanitz 1997).

In terms of satisfaction levels for the provision of laboratory services, TAT is quite often the primary measure of performance utilised. The obvious benefits of a faster TAT include more efficient patient management and quicker clinical intervention, which for many time-critical conditions are a major factor in the level of quality of care provided and the subsequent quality

of life of the patient post-treatment. Clearly, the reduced levels of morbidity and mortality that result from faster test result TAT are a major aspect in this respect.

The definition of a specific TAT value has 3 components; pre-analytic, i.e. collection of the sample and its transport to the laboratory; analytic, and; post-analytic, i.e. the communication of the test results to the ward or individual clinician. There have been some successful solutions with regard to improving the TAT values within the central laboratory service within hospitals and clinical centres, including; pneumatic tubing systems; decentralised testing such as satellite laboratories and Point-of-Care Testing (POCT), and improved information technology (IT) (Manor 1999).

Pneumatic tubing systems are interconnecting arrangements of tubes joining the various clinical areas of a hospital building to the centralised analysis laboratory facility that have been proven to be successful in reducing the pre-analytical phase of TAT (Fleisher, Schwartz 1995, McQueen 1993, Green 1995). Not only can this method potentially save time in the transport of samples to the laboratory, it can also relieve the requirement for personnel to carry-out this role in person. The benefits in terms of efficiency of this diagnostic system TAT process are therefore obvious, albeit that they are somewhat limited in terms of overall additional value achieved in terms of the accuracy of the test itself.

By comparison, decentralised testing is based on a twofold ideology vis-à-vis; firstly, through the use of satellite laboratories distributed throughout the hospital or clinical institution and, secondly; via the use of POCT technologies that directly undertake the diagnostic testing of specimens in a 1-step process close to the patient. Hence, decentralised testing seeks to move testing (back) to the site of patient care, which raises obvious issues in that it is very much against the trend of centralisation that evolved throughout the majority of the 20th century. Setting up such satellite laboratories in areas where rapid patient care is essential, i.e. in the Emergency Department/Room (ED/R) can help reduce the pre-analytical phase of TAT. However, it is recognised that post-analytical issues may still persist. Furthermore, satellite laboratories have been found to often duplicate services that are already provided by the central laboratory service (Manor 1999) which can therefore result in obvious economic inefficiencies.

Improved IT serves primarily to address the post-analytical phase of TAT with respect to the effective and timely communication and review of diagnostic test results. Computerisation of information systems reduces the risk of human error in the delivery of test results. Furthermore, the instantaneous nature of computer-based reporting has been found to significantly decrease the time with respect to the reviewing of results (Bluth, Lambert et al. 1992).

1.4 Development of POCT

Historically, the availability of key technologies has been the main factor in determining where and how diagnostic testing would be performed. For example, large and complex biochemical analysers are most efficiently utilised in a centralised environment. In this regard, batched testing allows for an economy of scale to be achieved and quality control systems to be developed and implemented successfully (Kost, Ehrmeyer et al. 1999). Technological advancements that occurred in the late 20th century in areas such as microfluidics, biosensors and biomarker development have allowed for the development of a range of so-called Point-of-Care Testing (POCT) devices, which have permitted the relocation of diagnostic testing back to the site of patient care. POCT was developed with the aim of reducing test TAT via providing for the collection, analysis and review of results within minutes (Manor 1999). In this regard, it seeks to accomplish more effective patient management leading to increased quality of care while attaining economic savings through the reduced length of stay for patients in hospitals (McDonald, Smith 1995).

At the outset of the implementation of POCT, simple chemical test methods were used in a strip-based format by clinicians and nurses, with such non-invasive procedure requiring little, if any, expertise. With the ongoing development of more sophisticated technologies that now underpin the new generation of POCT devices, issues have emerged with respect to clinically acceptable accuracy levels in terms of test sensitivity when compared to the technologies utilised within a central laboratory service (Huckle 2008).

Early POCT devices were not without their flaws, design issues made it difficult for device operators to utilise the devices in a reliable manner in order to produce results of adequate quality (Lewandrowski, Gregory et al. 2011). The issues surrounding both the number and complexity of the steps required to be performed by the POCT operator resulted in the opportunity for a high number of user errors that can directly affect the quality of test data produced. Furthermore, issues involving the lack of an electronic data management system and the absence of safeguarding mechanisms to control who operates the devices, including issues such as the use of inappropriate test strips, have traditionally been problematical (Lewandrowski, Gregory et al. 2011).

Due to the initial issues that limited the functionality of POCT devices and the quality of the associated data, the growth of the sector was somewhat modest at first. However, with advances in both the technology and the way by which it is provided, the prevalence of POCT has increased significantly over the last decade. Growth rates in uptake are increasing steadily in terms of use, particularly within the United States (Larsson, Greig-Pylypczuk et al. 2015). In terms of a global perspective, it is estimated that the worldwide market for POCT was almost

$15.1 billion in 2012 and is predicated to reach $19.3 billion by 2018 (Point of Care Diagnostics, BCC Research, 2014). It is, however, important to recognise that POCT exists as 2 different market sectors, namely the "professional market" (incorporating testing within clinical settings in areas such as critical care, infectious disease, cardiac markers, diabetes, lipids, coagulation and haematology) and the "non-professional market" (incorporating "over-the-counter" POCT including home glucose monitoring and pregnancy tests). The "professional market" was estimated to be worth $5.66 billion in 2011 and was projected to grow to $6.76 billion by 2016 (St John, Price 2014). The POCT market therefore can be seen to be currently dominated by "over-the counter" and home-use products which can be utilised with minimal need for regulation.

1.5 Technologies Underpinning the Implementation of POCT

To understand the fundamental technologies that underpin POCT, it is firstly necessary to determine its different configurations. In this respect, the concept of its utility can occur in 2 differing forms; vis-à-vis a handheld format (i.e. bedside device) or a desktop analyser format (i.e. near-bedside device). It should be noted that the desktop configuration of POCT analysers remains significantly smaller in size compared to that of a typical analyser found in the central laboratory. The technology utilised to develop POCT has been further influenced by several key operational requirements, namely; the devices should be simple to use; reagents and consumables should be easily stored with relatively long shelf life; results should be comparable with those from an established central laboratory service method and, finally; all components of the device and the test method itself should be safe to use (Price, St John et al. 2010). A general realisation is that the handheld format of POCT primarily incorporates the use of (bio)chemically-responsive strips (both quantitative and qualitative) while the desktop-format will tend to utilise more complex built-in microfluidics, not dissimilar to those present in the corresponding central laboratory apparatus.

Bedside POCT devices are generally handheld systems that range from small dipsticks, of the type used for basic urinalysis, to dedicated test cartridge-based devices, such as those used for blood gas analysis. Handheld devices often entirely negate the need for specific sampling, labelling or transport of specimens by utilising direct interventions such as "finger-stick" capillary sampling techniques for blood analysis (St John, Price 2014). Dipstick devices are the most basic form of POCT that can incorporate a reagent that responds directly to a targeted analyte. Whereas, they can simply involve a visual colour change, they more commonly involve the use of reflectance technology or fluorescence spectrophotometry (in the case of immunosensors) to provide an estimate of the amount (concentration) of the analyte that is present in the sample. The most popular form of a device that incorporates a test strip is that

used with a glucose meter, which dominates the testing area with respect to the management of insulin dependent diabetes. These particular meters commonly use photometric or electrochemical detection systems in order to provide a measurement of blood sugar level to the device operator (patient). International normalised ratio (INR) measurement in the management of patients on warfarin (anticoagulation) therapy is a further area associated with the intensive use of handheld test-strip based POCT technology, which again incorporates the use of optical and electrochemical detection (St John, Price 2014). With respect to the category of devices with dedicated test cartridges, these tend to utilise some sort of sensor substrate and microfluidic technology. The benefit of a cartridge/reader device is that an extensive testing menu can be made available through the use of a single device capable of operating with a number of different cartridge-based tests.

Near-bedside devices are commonly desktop POCT devices which share common operating principles with a number of central laboratory test devices. In essence their purpose is to migrate the laboratory service to areas of clinical need, where space tends to be at a premium and operators will normally be non-specialists. Therefore, desktop POCT devices have followed a general trend of miniaturisation and increasing computer processing power in order to meet the diagnostic requirements (St John, Price 2014). The continued technological development of microfluidics has therefore been key in this respect. Microfluidic devices have several innate advantages in their use, the most notable of which are a low sample and reagent volume, high capability of integration and small feature sizes (Jung, Han et al. 2015). The most prominent desktop POCT device are those for the analysis of blood gas composition and associated concentration parameters. These devices also tend to utilise test cartridge technology, and so are different to the handheld devices in that the sensors here are designed to be re-usable in this configuration (St John, Price 2014). Again, this has the benefit of allowing for a single device to provide an extensive testing menu to the area of critical care in which it is located.

1.6 Benefits Potentially Available through POCT

The potential clinical benefits that are available through the use of POCT depend upon the setting in which they are employed, i.e. use for self-testing in primary care or as a directed diagnosis routine in secondary care. In a wider sense, POCT represents an advancement in healthcare provision and hence contributes to the realisation of health service reform targets within the processes being undertaken by governments globally. All of these stakeholders share a number of many common ambitions, including; improving access, increasing quality of care to all sectors of society, reducing costs and becoming more patient-centred (Price, St John 2012).

With regard to self-testing, POCT can bring the obvious benefit of self-management of a condition by the patient themselves, reducing the requirement for regular visits to a general practitioner, saving time and increasing convenience for both the patient and clinician. Furthermore, increased education and awareness of a condition can subsequently increase adherence to a treatment regime and therefore lead to more effective control of disease or condition (Price 2001).

Much of the established research on the use of POCT in primary care has indicated that it is of limited value in terms of improving clinical outcome (Price 2001, Grodzinsky, Wirehn et al. 2004). Notwithstanding these limitations, POCT use in primary care has the potential to provide benefits in terms of patient satisfaction and organisational efficiencies. However, the clinical outcome benefits of POCT, often arising from an earlier intervention in a time-critical situation, are difficult to obtain as these occurrences are much less common in primary care settings (Junker, Schlebusch et al. 2010). As such, it is proposed that quite radical system-level changes would be required in order to allow primary care clinicians to take full advantage of the benefits that are potentially available through the use of POCT. Many of the issues that need to be considered to create this environment relate to workload, reimbursement and clinical governance, all of which are more difficult to attain control of in primary care (Turner, Van den Bruel et al. 2016). The rapid TAT associated with POCT can make it an effective and quick rule-out method for certain conditions thereby negating the need for further tests and shortening the length of time to a successful diagnosis. Overall, it is difficult to gauge whether or not POCT can provide a cost-effective solution within primary care, as its success or otherwise is heavily influenced by both the health system environment and the particular type of test in question (Laurence, Moss et al. 2010).

In the secondary care setting the intrinsic nature of POCT serves to improve TAT values through the reduction of a number of pre- and post-analytical steps such as sample transport, sample preparation, data entry and the forwarding of test reports to clinical specialists. In a hospital setting, the use of POCT has therefore a number of consequences, including; quicker clinical intervention, improved patient management, reduced hospital length of stay, reduced opportunity for pre/post analytical errors and a less invasive test method.

In the case of a critically ill patient, faster clinical intervention via the improvement in the TAT offered by POCT can have a significant impact on the achievement of a successful clinical outcome. This is particularly in the case for a time-critical condition such as acute coronary syndrome (ACS) where more rapid intervention can have a major effect on improving morbidity and mortality rates. With traditional testing that utilises the central laboratory service, such a patient's condition, as indicated by analysis of their blood, urine, etc., may have already changed

significantly by the time a test result is received, resulting in a possibility of a critical clinical decision being made with out-of-date information and hence increasing the risk to the health of the patient. Therefore, the provision of real-time data through the use of POCT is seen as being more beneficial clinically despite any potential minor reduction in the analytical capabilities that such devices may have in comparison to those utilised in the central laboratory (Harvey 1999). Furthermore, the use of POCT during surgery can reduce theatre time and patient blood loss through improved test TATs, which then has a subsequent positive effect by way of reduced post-operative recovery for the patient (Price 2001). As a specific example, cardiopulmonary bypass patients are at increased risk to excessive perioperative blood loss and subsequently there is a possible requirement for blood transfusion. Blood component administration (i.e. heparin anticoagulation) can be used to reduce blood loss and hence minimises the requirement for transfusion, however, dosage control of this therapeutic method is an empiric technique related to the TAT of laboratory tests. Rapid POCT devices can be used in this regard to provide more targeted and precise administration, hence minimising the potential for blood loss and the associated need for transfusion (Despotis, Joist et al. 1997).

This form of timelier clinical intervention also leads to the subsequent benefit of improved patient management, in that it allows for transfer of the patient through the clinical pathway in a more efficient manner, hence allowing the clinical institution to be more effective in the utilisation of its resources. POCT has the potential to reduce both the number and complexity of the diagnostic tests carried out which can result in a reduction in the requirement for other forms of laboratory evaluation. This can then provide for a more effective use of resources i.e. personnel, equipment, clinical space etc. (St-Louis 2000). Incorporation of POCT into existing clinical pathways allows for the rapid progression of the patient when test results lie within an expected range. Also, in the case of an unexpected result, intervention can occur at the earliest opportunity (Harvey 1999). Overcrowding (especially in the ED/R) and prolonged waiting times within hospitals have been linked to adverse clinical outcomes in addition to decreased patient satisfaction. Improved patient management through the use of POCT has an obvious role to play in addressing such issues (Larsson, Greig-Pylypczuk et al. 2015).

More effective patient management often results in a reduction in the length of stay in hospital for patients. This is seen as one of the primary advantages of POCT use, particularly in the context of the immediate and direct benefits of early intervention (Price 2001). The benefits of a reduction in the length of stay in hospital are twofold, firstly; the levels of patient satisfaction will be improved with the more effective management of the clinical episode and, secondly; there will be a more effective use of the limited resources available which can result in an economic benefit for the clinical institution.

Improvement of test TAT values via the reduction in number of steps associated with analytical testing can clearly result in a reduced risk of operator error in both the pre- and post-analytical phases. For example, the use of POCT can reduce the risk of placing a specimen within the wrong sample tube and/or incorrectly transcribed results (Harvey 1999). Furthermore, the use of POCT negates the requirement for sample transport which, for example in the case of blood gas testing, overcomes issues regarding the possibility of induced sample instability that may occur during the journey to the central laboratory.

POCT can often provide diagnostic results using only microlitre volumes of blood, i.e. just a few drops, hence making it less invasive. This carries the obvious benefits to both the patient and device operator of convenience and satisfaction. Furthermore, due to the significant reduction in sample volumes required in comparison to Central Laboratory Testing (CLT) methods, the use of POCT can reduce the risk of iatrogenic blood loss and associated anaemia, while also conserving blood products that potentially would be required for transfusion purposes (St-Louis 2000). The use of microlitre sampling volumes has also been shown to both significantly reduce the amount of blood lost by a patient thereby removing the requirement for a blood transfusion to be administered (Tinmouth, McIntyre et al. 2008). In terms of safety, POCT methods can also reduce the risks involved in contact of patient blood with the device operator (Harvey 1999).

1.7 Recognised Failings of POCT in Secondary Care

Despite the benefits and potential for improved clinical outcomes offered by the use of POCT devices in secondary (hospital) based healthcare their uptake and use within has not been without issue. First generation POCT devices suffered from a number of problems related to an inconsistency in device performance and hence problems in attaining reliable results. The operation of such devices required a relatively large number of steps to be performed and hence this introduced the opportunity for user error (Lewandrowski, Gregory et al. 2011). Clearly, any actions that might be taken by a clinician based on an erroneous test result can have severe implications, particularly within the secondary critical care setting. Therefore, these issues had a significant impact upon trust and confidence with the use of early POCT devices used for diagnostic testing. The lack of an electronic reporting system and the absence of safeguarding controls to ensure operator competency also contributed to the conditions necessary for a quality of result to be produced. One particular concern in this regard was the possibility of inappropriate use of the test strip/reagent (Lewandrowski, Gregory et al. 2011).

The more recent generation of improved POCT devices and their associated diagnostic protocols have sought to overcome these issues and hence uptake of these systems has increased. However current research indicates that manufacturer expectations for their continued uptake

are not being met in a significant proportion of major hospitals in the United States (Loten, Attia et al. 2010). To date, studies have not been able to ascertain the reasons for this less than expected growth in the utilisation of POCT devices. It is possible that the negative clinician perceptions of and a lack of confidence in these technologies is still a major underlying factor that limits the uptake of POCT. It is suggested that concerns over the accuracy of the resulting data attained in a non-emergency situation have also acted to slow the adoption of POCT (Larsson, Greig-Pylypczuk et al. 2015). While some evidence is provided with respect to manufacturer's expectations, the notion that the uptake of POCT in secondary care is less than what was expected moving into the 21st century, as far as clinicians are concerned, is intrinsically difficult to provide an evidence base for as no such base of data exists.

A significant challenge that continues to face the application of POCT in the secondary care setting is the provision of a very reliable and accurate diagnostic testing system by way of the existing central laboratory service. Despite the fact that the central laboratory in many ways exceeds the actual clinical need, the expectation remains that POCT will replicate this performance with a significantly reduced TAT value. Substantial research has been carried out comparing the analytical performance of POCT with that of the equivalent CLT provision and has highlighted a variable and/or reduced performance of POCT (Hjortshøj, Venge et al. 2011, Khan, Vasquez et al. 2006, Shephard, Whiting 2006, Dommelen, Tiel et al. 2010, Lenters-Westra, Slingerland 2009). It is noted that such variance or reduction in performance has a number of possible causes including the use of whole blood as the test sample (rather than determination made from serum or plasma) and the use of novel sensing technologies such as electrical conductivity as a measurement parameter (St-Louis 2000).

Whereas, initially it was the technological aspects of POCT that have tended to attract attention, currently the emphasis has shifted to how and where it should be applied in order to best attain the recognised benefits that it presents. Therefore, it is being increasingly accepted that technological factors alone are no longer the primary underpinning issue with regard to explaining the limitations of POCT device uptake within the hospital-based healthcare environment. There have been indications that despite the use of POCT to reduce TAT values within secondary care, this hasn't translated into a positive impact on clinical outcome. Research has also found that, within the ED/R environment, the quicker availability of test results from POCT has not led to a reduction in admissions or associated length of stay for patients. This therefore suggests that the availability of test results from POCT devices are not the principal factor that is restricting the progression of a patient through the care pathway (Kendall, Reeves et al. 1998). Hence, in reality the indication is that the potential benefits available through the utilisation of POCT are negated somewhat due to the limited effect of

improved TAT values on the overall clinical outcome. In a broader sense, it is therefore the ability of the clinical pathways to take advantage of the improved TAT values that will ultimately determine the effectiveness of POCT in practice with respect to workflow and patient care. Benefits such as reduced admission and/or length of stay in hospital and the improved clinical outcomes are seen as being highly dependent on several factors which vary across healthcare settings. As such, the real-world implementation of POCT is a much more complex process than it might at first seem (Larsson, Greig-Pylypczuk et al. 2015). For example, delays in radiology testing have been shown to extend the total length of stay within critical care areas such as the ED/R (Miele, Andreoli et al. 2006). Thus, in these circumstances any improvement in the test TAT is negated entirely.

In this respect, there is an ongoing debate as to the true value of POCT within the secondary healthcare system. In particular, this relates to how it should be integrated within the clinical care pathways. This is in a stark contrast to the broad acceptance of POCT that is apparent in the self-testing (primary care or home-based) environment, specifically with regard to blood glucose testing for diabetics, INR monitoring for patients receiving anticoagulation therapy, and pregnancy/fertility tests. The successful utilisation of POCT within this sector clearly verifies the benefits that this particular type of patient-centric testing can bring with respect to the miniaturisation of analytical instrumentation in order to manage a chronic medical condition or disease in a more effective manner. It is therefore apparent that the various factors restricting the more widespread adoption of POCT within the clinical environment are not really well understood. Hence, the work reported in this thesis therefore seeks to address the nature and scale of the issues that affect POCT uptake and usage in secondary care. For the purposes of the study, such factors are suggested as being barriers to the more widespread uptake of these devices. It is therefore proposed that a better understanding of their origin and source will lead to solutions that enable the more effective utilisation of POCT in hospital-based care for the direct benefit of patients.

1.8 Development of the Research Aims & Objectives

It is widely recognised that the uptake of POCT and, importantly its utilisation within the clinical environment, is lower than might be expected. The nature and relative importance of the issues (real or perceived) that have been identified as being possible impediments to the more widespread adoption of POCT are not fully understood. Indeed, much of the information that purports to describe the inadequacies of POCT devices would seem to be anecdotal in nature with most lacking any form of primary data to back up these claims. Hence, it is important to understand the precise origins of such impediments to POCT uptake in order to enable an appropriate assessment of their utility to be undertaken.

Thus, the central aim of this research is to better understand and categorise the core issues that have been identified as impeding the clinical uptake of POCT in a hospital-based environment, i.e. the barriers to adoption. Furthermore, this research aims to assess these identified impediments from a global perspective by considering any role that the nature of the funding of the healthcare process (i.e. free at the point of delivery versus insurance based) has on the findings. In doing so, key objectives of the research are:

- To determine from a systematic review of the academic literature the actual issues that affect the adoption of POCT devices within the hospital-based clinical environment;
- To categorise the issues identified from the literature as a means of understanding in detail their relative contribution to adoption of POCT devices in the hospital environment;
- To determine, in order of priority, which issues are currently impacting the adoption of POCT devices within the clinical environment;
- To determine the relationship between those issues identified from a consideration of the academic literature and the opinions of clinicians within the UK healthcare environment on the same issues;
- To compare and contrast clinical perspectives (opinions) on those issues that are seen as impediments to the uptake of POCT from clinicians working in the UK healthcare system, i.e. that is free at the point of delivery, with those in the US system where the cost of healthcare provision is insurance-based;
- To assess how the perception of issues effecting the uptake of POCT, including their impact and relevance, varies with respect to the specific clinical role;
- To determine the global experiences of clinical bioscientists, as the professional group most closely aligned to hospital based diagnostic testing, in relation to the identified barriers to adoption of POCT;
- To identify the key advantages and potential benefits of POCT use within secondary healthcare;
- To identify the major disadvantages deemed to result from the use of POCT;
- To determine the clinical areas/situations in which POCT can provide the most benefit in secondary care;
- To suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption?

1.9 Layout of the Thesis

The research outcomes of this thesis are presented in a total of 8 chapters, including this introduction to the work. Given the nature of the project objectives, Chapter 2 presents the Methodology and Chapter 3 the Literature Review. The decision for this order is based on 2 important considerations; firstly, primary data on the barriers to adoption of POCT within secondary (hospital) care is particularly scarce and so a method to appraise and categorise the key areas for consideration from published sources is required prior to undertaking the literature review itself and, secondly, since assessment of the available literature will form the foundation of the research on clinical opinion of POCT uptake this should be carried out in a systematic way and so the findings from the literature review that are presented in Chapter 3, are essentially the first of the results chapters. With this in mind, the overall layout is as follows:

- Chapter 1 – Introduction to the Research
- Chapter 2 – Research Methodology
- Chapter 3 – Systematic Narrative Review of the Published Literature on Barriers to the Clinical Adoption of POCT within the Hospital-Based Environment
- Chapter 4 – Clinical Perspectives on Barriers to Adoption of POCT from within the UK National Health Service (NHS)
- Chapter 5 – Clinical Perspectives on Barriers to Adoption of POCT from within the US Health System
- Chapter 6 – Perspectives on Barriers to Adoption of POCT from within the Global Clinical Biosciences Cohort
- Chapter 7 – Statistical Analysis
- Chapter 8 – Conclusions and Recommendations for Future Work

Chapter 2

Research Methodology

2.1 Research Design

In order to achieve the key objectives of this research, as set out in Chapter 1, a research methodology has been adopted that provides for the identification of, and the collection of clinical opinion on, barriers to adoption of point-of-care testing (POCT). The systematic nature of the research design is adapted from the model proposed by Saunders, Lewis and Thornhill as a means of guiding business research (Saunders, Lewis et al. 2015). This method is known as "the research onion" and represents a means of describing the different layers of a research process, as illustrated in Figure 2.1. Due to its systematic nature, it has a high level of adaptability and can be used in a variety of contexts (Bryman 2015). Working from the outside inwards, the model follows a progression by which the research methodology can be designed, with each layer representing a more detailed stage of the research process.

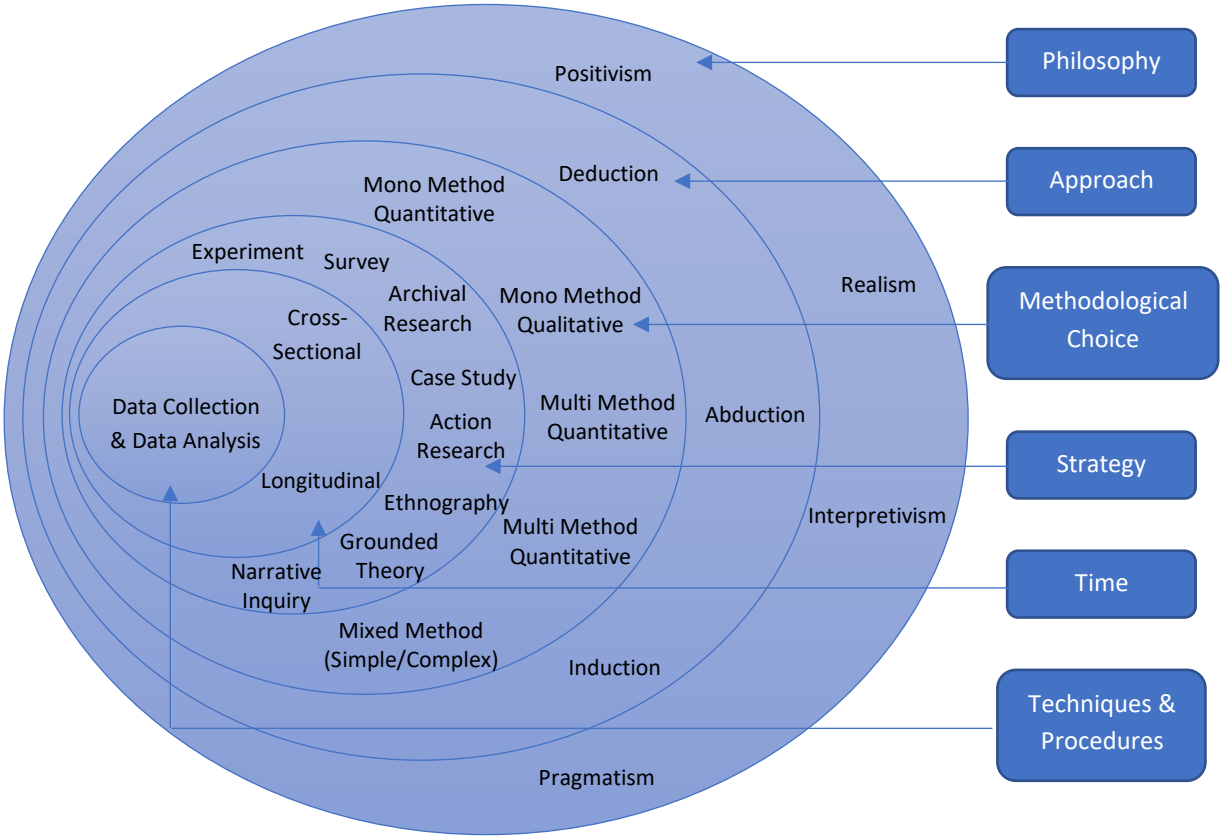

Figure 2.1 – Schematic representation of the Research Onion Model (Saunders, Lewis et al. 2015).

2.2 Research Philosophy

The research philosophy adopted influences the assumptions that can be made and how data is both collected and analysed. There are various philosophies that may be applied with respect to attaining the objectives of a project and hence that which is employed will influence how the research will be conducted (Goddard, Melville 2004). It is therefore important to be aware of the philosophy that is being applied and to ensure that it relates directly to the intended aim of the research. A series of 4 core philosophies were considered for the research to be undertaken here and the merits of each appraised in the context of how well it can provide for the required outcomes to be achieved.

Positivism uses the natural sciences as a fundamental focus to explain how and why things happen through measurement, statistical logic and verification. It lends itself very much to quantifiable observations. Therefore, a positivist approach will generally involve the collection of large data sets that will lead to easily-comparable information. The key advantage of positivism is that there is a clear theoretical focus to the research and this allows for a high degree of control of the process. However, this philosophy can also have significant limitations when an understanding of social processes is required and how these can be perceived, including the subsequent variation across individuals and associated relationships. Therefore, the positivist philosophy is essentially focused on facts (Wilson 2014).

The philosophy of interpretivism is focused on understanding using the qualitative tools of the social sciences. As such, it relies on the interaction between a trained researcher and a subject as a means of measuring some phenomena, and so typically involves the use of both observation and interviews. Sample numbers tend to be smaller than in a positivist philosophy with emphasis more on elucidating a meaning and understanding from the data. The interpretivist philosophy is much more adaptive to change than positivism and allows for circumstances that are more complicated and contextual. However, data collection can be complex and time-consuming, and there is uncertainty with regard to the findings that may or may not appear as a result. Nevertheless, in the right circumstances it allows for the consideration of how individual people differ and hence goes beyond the simple reporting of observable objects (Saunders, Lewis et al. 2015).

In addition to positivism and interpretivism there is also realism and pragmatism. Realism is another scientific philosophy and so can overlap with positivism somewhat. It is again based on data collection and tends to use high sample numbers with the collection process usually highly structured. Realism (specifically critical realism) accepts that deceptions exist and that factors may occur between the researcher and subject based on their individual reality. This approach

can influence the relationships between individuals and the wider groups to which they belong, thereby providing a way to engage in multi-level research (Novikov, Novikov 2013).

By comparison, the pragmatic research philosophy is one that overlaps aspects of both positivism and interpretivism, with the research question then being central to the design of the research tools employed. Pragmatism recognises that there are many different ways of interpreting research findings, that no single point of view can ever give the entire picture and that there may be multiple realities that need to be considered (Saunders, Lewis et al. 2015).

The interface between the natural and social sciences is becoming increasingly blurred within healthcare research. There is now an understanding that user/patient perspectives must be considered appropriately when assessing health services and the utilisation of technology within such. For example, it is now recognised that the use of quantitative methods alone, such as basic questionnaires, fail to allow for an appropriate qualitative analysis and may miss rich insight on participant experience (Kuljis, Money et al. 2016). Although much of the work to be carried out in this research is to be interpretive in nature, a number of the methods employed need to be more quantitative in order to progress the research effectively. Therefore, although small sample numbers and qualitative studies may be appropriate in parts of the overall work programme, larger numbers and a more quantitative approach are needed to deliver an understanding at a more specific level. Hence, based on these considerations, a pragmatic philosophy has been adopted here.

2.3 Research Approach

There are 3 main research approaches that can be used to further the objectives of this work; deductive, inductive and abductive. A consideration of the fit of each process to effectively deliver the research outcomes of interest here was undertaken. Deductive research concerns creating a hypothesis that is based on a pre-existing theory and subsequently designing research to test it (Silverman 2005). The deductive approach is often employed with a positivist philosophy that uses statistical analysis to test the hypotheses by determining if results lie within the expected boundaries.

While the deductive approach is seen as being top-down, the inductive approach works in the opposite direction. This approach utilises observations rather than theory as its starting point, wherein data are used to search for patterns and connections. As a result, there is often no framework that defines how data are to be collected, but rather the focus of the research is to acquire data that might then subsequently be connected via some theoretical basis (Flick 2011).

By comparison, an abductive approach utilises the most likely reasoning that can lead to a rational solution (Bryman, Bell 2015). Hence, the abductive research approach uses observations to give the best prediction of a solution to a problem.

Based on a consideration of these various attributes, the research to be undertaken here will utilise an inductive approach in that it uses observations associated with the barriers to adoption of hospital-based POCT to determine their relative validity across clinical sectors. In doing so, the primary data obtained will be used to better understand and categorise the various contributory issues that have been identified as being impediments to the clinical uptake of POCT. In this way, the research objectives as set out in Chapter 1 will be achieved. The advantage of applying an inductive approach here is that it allows for conclusions to be drawn from sometimes incomplete observations.

2.4 Methodological Choice

After deciding on the research approach, the next layer of the "research onion" involves the determination of the actual types of research methods to be used in order to conduct the investigation. Essentially, this process of research design considers whether qualitative or quantitative methods will be used, or if a mixture of both is required. In this regard, a "mono" study will only use the one type of data collection technique, be it quantitative or qualitative while a "multi" study uses more than one quantitative or else more than one qualitative technique. A "mixed methods" approach uses both qualitative and quantitative techniques to analyse the research data.

As indicated earlier, quantitative research techniques better lend themselves to studies that generate large amounts of data, so that statistical methods of analysis can be used effectively (May, 2011). Qualitative research presents the challenge of the data being defined by the number and type of respondents or objects being studied. A means to control widespread variation in the responses received is to use scripted interviews or text questions. This, coupled with targeted open-ended questions that allow the respondent to expand further on the more specific information sought, can enhance the scope of the process substantially. Qualitative techniques are often used to study social phenomena (Feilzer 2010) but can also be adapted to attain and interpret more specific responses such as clinical opinion.

Based on these considerations, mixed methods are to be used in this research. This approach provides a number of advantages, in that it fits well with the pragmatic philosophy of this research, i.e. allowing the research question to frame how the methodology will develop. Secondly, this is a flexible approach that can be applied to a range of stages of a complex investigation. Furthermore, this approach will allow for the comparison to be made of results

obtained from studies employing both large and small sample sets. A mixed methods approach has been utilised in healthcare research before, specifically with regards to understanding barriers to organisational adoption of technology within the medical sector (Paré, Raymond et al. 2014), and hence this choice of method is validated somewhat. To this end, the mixed methods research can be conducted in both a simple or complex manner. A simple mixed methods design involves the use of one type of research technique followed by the other, for example an observation study (qualitative) followed by a survey study (quantitative). As a development of this approach, a complex mixed methods design involves using quantitative techniques to analyse qualitative data. For example, quantifying the number of responses in a series of interviews that fall within a particular category of answer. As such, it is this complex mixed methods design that will be used in this research. The advantage of this approach is that quantitative data that reflects the point-of-view of participants can be presented in a clear and concise manner.

2.5 Research Strategy

If required, study design can avail of multiple strategies in order to address the research question and so the research should not be limited as such (Saunders, Lewis et al. 2015). In the "research onion" model there are 8 strategies including: A survey strategy, where structured studies can be used to collect large amounts of data from participants, who are often sizeable in number. An experimental strategy, to compare results with expected outcomes in cases where these are known. An action strategy, that aims to bring about change using the results and findings from the research carried out and that analyses current practices to determine if they exist as the most ideal approach. A case study strategy which, as the name suggests, focuses on a particular scenario to draw conclusions, for example to draw generalisations or perhaps to determine differences between specific conditions (Bryman 2015, Silverman 2005). Grounded theory utilises qualitative data and is frequently used in the field of social sciences research (Bryman 2015). This strategy does not use preconceived theories to determine the research but instead uses the research question to define the methodology (and so is often used within the pragmatic philosophy). As such, grounded theory investigates actualities in the real world and analyses these without any preconceptions. This is often achieved through the use of interview survey studies (Allan 2003). Ethnography focuses on the study of people or cultures, where the researcher takes the point of view of the subject that they are studying. A close observation of individuals or societies can aid understanding of cultural relations and perspectives (Bryman 2015). An archival research strategy involves the use of existing materials to conduct research and form conclusions (Flick 2011). For example, this may be through the application of a systematic literature review, i.e. using previous bodies of information to collate

data and analyse it appropriately. The final research strategy here is the narrative inquiry strategy which utilises qualitative information such as letters, autobiographies, conversations, interviews, etc. to understand how individuals can create meaning and understanding through previous narratives (Clandinin, Connelly 1999).

Based on these considerations, multiple strategies will be implemented in this research in order to meet the objectives as defined in Chapter 1. An archival research strategy will be employed in order to fully understand and categorise the indicated barriers to adoption of POCT within the relevant knowledge base. Both survey and grounded theory strategies will be used to collect data from clinical professionals participating in the study, which aligns well with the pragmatic philosophy employed. These strategies will be used to attain the opinion of the clinicians with respect to adoption and utilisation of POCT. Furthermore, since a solutions-based approach is underlying this research it is therefore hoped that findings can be used to stimulate action within the relevant healthcare bodies and device industry in regard to how POCT is employed, and hence an action research strategy is also required here.

2.6 Time Horizon

The time horizon for the research simply refers to the period over which the research is concerned. A cross-sectional perspective provides a snapshot of a situation at a given time. Hence, it will report in the context of how phenomena exist at a certain point of time or over a specified period. For example, a longitudinal time horizon involves data being collected over a significant time frame and can hence be used to assess changes over this period (Goddard, Melville 2004). Although this research will involve archival research over an extended period of time through the application of a systematic literature review, the primary survey-based research to be carried out will be cross-sectional in nature. This approach will allow for the primary research findings to be compared to those issues deemed to be impeding the implementation of POCT within hospitals as determined from consideration of the published literature over an extended period. Hence, solutions to overcoming these barriers can be developed in terms of the experience of those who use them directly.

2.7 Techniques & Procedures

The core of the research onion model considers the techniques and procedures to be used to collect the data required to conduct the research investigation. In the context of this work, the initial step in devising solutions to overcoming the barriers to adoption of POCT is to firstly fully understand the barriers that have been identified by experts in the field. Therefore, a systematic literature review will be carried out in order to frame and collate the types of barrier concerned.

This information will be used to develop the survey tools needed to attain the data for analysis that form the foundations of the research process.

The primary data needed to obtain a cross-sectional snapshot of the current situation regarding the uptake of POCT will be facilitated by a set of well-defined survey tools. These will be used to acquire primary data from healthcare clinicians through both face-to-face interviews and on-line questionnaires. By way of following the pragmatic philosophy of this research, the secondary data gathered by the systematic literature review will be used to frame the on-line survey and interview studies so that they can directly attain the key primary data needed. The complex mixed methods approach leads to the choice of both survey and interview studies. While the survey studies will be used to increase participation and hence achieve the required sample numbers, the interview studies will be used to accumulate vital qualitative information in order to add value to the quantitative data collected through the surveys.

It is recognised that employing 2 methods of data collection gives rise to the potential that each method could influence participant response to the survey. A main advantage of online survey tools is that interviewer effects are avoided (Duffy, Smith et al. 2005) and hence there can be no interviewer influence and/or bias affecting participant response. However, a serious issue with online survey studies is the methodical difficulties in determining population and random samples (Dillman, Bowker 1999). For the purpose of this piece of research, both streams of data are to be analysed as being the same, with neither stream being afforded a stronger weighting of value over the other in terms of the responses given. However, the face-to-face aspect will allow for more detailed explanation of certain responses, in which some specific pieces of information of high value can be collected. In order to ensure the 2 streams of data can be considered as a uniform data set an appropriately managed assessment of the survey responses collected by the study through both channels is to be undertaken. This process of analysis is required in order to determine if these data can be amalgamated with sufficient integrity, with the distribution of scaled responses to be analysed and compared appropriately.

Quantitative methods will be used to analyse the qualitative data in order to identify key trends in the data. These techniques are expected to accommodate the solutions-based ideology of this research and allow for conclusions to be derived that will enhance POCT utility in hospital-based healthcare. This reflects the inductive approach of the research with the observations made forming the foundation for key patterns/connections to be identified accordingly.

2.8 Realisation of Research Objectives

The methods employed by this research must directly act to achieve the research objectives as described in Chapter 1. A brief summary of how the methodology developed will attain such targets is described here:

- To determine from a systematic review of the academic literature the actual issues that affect the adoption of POCT devices within the hospital-based clinical environment;
- To categorise the issues identified from the literature as a means of understanding in detail their relative contribution to adoption of POCT devices in the hospital environment;
- To determine, in order of priority, which issues are currently impacting the adoption of POCT devices within the clinical environment;

The first 3 research objectives are serviced by a longitudinal time horizon as a means of identifying and understanding the barriers to adoption of POCT that have been raised by experts in the sector throughout this century. A systematic review of the relevant academic literature is to be implemented to identify and subsequently categorise such issues. An assessment of frequency, in terms of citation within the relevant knowledge base evaluated, will be used to attain a measure of priority (in terms of current impact upon adoption) that issues hold.

- To determine the relationship between those issues identified from a consideration of the academic literature and the opinions of clinicians within the UK healthcare environment on the same issues;

Primary data will be attained through the use of survey studies based upon the findings and assessment of the systematic literature review. The first of which, executed with a sample of UK clinicians, will be used to validate findings and add a cross-sectional dimension to the time horizon of the research, providing insight into the current situation with respect to clinical opinion on barriers to uptake. The purpose of this study is to determine which barriers identified within the literature exist in reality (at least within the UK NHS) and which are perhaps historical barriers that have been fully or partly resolved. Furthermore, the primary data will be used to validate and help determine the order of priority in terms of current impact upon POCT adoption, as addressed by the third research objective above. Mixed methods are to be exploited through the primary data collection of the research, using both face-to-face interviews and an online survey tool to both attain detailed narrative on responses whilst maintaining a maximum level of clinical participation.

- To compare and contrast clinical perspectives (opinions) on those issues that are seen as impediments to the uptake of POCT from clinicians working in the UK healthcare system, i.e. that is free at the point of delivery, with those in the US system where the cost of healthcare provision is insurance-based;

The UK study will be replicated almost identically within a sample of the US health system as a means of achieving this research objective. Again, this will be a cross-sectional study. The face-to-face aspect of the study design is to be maintained in order to preserve the rich information available through this method of execution. Findings of this study will be subsequently mapped onto the findings of the previous clinical study as a means of identifying similarities and any discrepancies between the primary data sets gathered.

- To assess how the perception of issues effecting the uptake of POCT, including their impact and relevance, varies with respect to the specific clinical role;
- To determine the global experiences of clinical bioscientists, as the professional group most closely aligned to hospital based diagnostic testing, in relation to the identified barriers to adoption of POCT;

As with the previous 2 primary studies, a third (almost identical) study, again based principally upon the findings of the systematic literature review study, is to be executed with the aim of satisfying these 2 objectives of the research. As the previous study investigates the influence of underlying healthcare model it is important that this 3rd study will negate such influences (if indeed, they do exist). As a result, this study is to be executed internationally by means of an electronic survey tool. This also carries the benefit of allowing maximum participation.

- To identify the key advantages and potential benefits of POCT use within secondary healthcare;
- To identify the major disadvantages deemed to result from the use of POCT;
- To determine the clinical areas/situations in which POCT can provide the most benefit in secondary care;
- To suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption?

While the 3 primary studies will be implemented to meet the research objectives as described above, all 3 will be designed in such a way that the findings of each can be amalgamated and assessed as a mean of achieving the final 4 objectives, as noted here. Primary data will be

collected in order to make an assessment on the key advantages/benefits and disadvantages of POCT, along with the clinical areas in which most benefit can be realised. Finally, the primary data will be used to make recommendations as to how the most significant barriers to hospital-based uptake of POCT can be potentially overcome.

In order to clarify findings somewhat, inferential statistics will be applied, where relevant, to the study responses. The association of categorical variables and the comparison of opinions between response groups will be statistically analysed using the Chi-square test and the calculation of odds ratios with 95% confidence intervals. Calculation of p-values using the Chi-square test will allow for the testing of a specific null hypothesis; a significant p-value (i.e. < 0.05) rejects the null hypothesis and, in doing so, answers 2 questions; what do the response results tell me about the population? And, what are the strength of such results? An odds ratio can be used to compare the responses of various groups, by dividing the odds of an event happening in one group by the odds of an event happening in the other. If there is no difference in odds, then of course the odds ratio would be 1. 95% confidence intervals can be applied to provide a guidance on the true odds ratio; that the figure would lie within this interval 95% of the time. Inferential statistics will be applied to clarify differences in responses, if any, potentially influenced by specific clinical role by analysing the responses from the different clinical groups within the primary studies. Furthermore, such methods will be applied, where appropriate, in a comparison of response profiles of the investigated study groups, i.e. UK vs US clinicians and Clinicians vs Clinical Bioscientists.

Chapter 3

Systematic Narrative Review of the Published Literature on Barriers to the Clinical Adoption of POCT within the Hospital-Based Environment

3.1 Study Objective

Advances in science and technology continue to play an integral role in the provision of effective healthcare. A detailed understanding of the pathologies and/or genetic disorders that give rise to various medical conditions is critical for the provision of appropriate and timely treatment. The benefits offered by new (and improved) diagnostic technologies for the management of diseases and attendant medical conditions are well established (Murray 1996, Fitzsimons, Sun et al. 2007, Rosenson 2010, Khan, Aurigemma 2012). However, it can be argued that the expense associated with their introduction is a significant factor in the continuing year-on-year increases in the cost of healthcare (Herndon, Hwang et al. 2007, Goyen, Debatin 2009, St John, Price 2013). Hence, it is clear that an assessment of the true utility of diagnostic testing platforms needs to be fully considered in an effective cost-benefit context. This is particularly the case for emerging technologies such as Point-of-Care Testing (POCT).

A major consideration for the realisation of global health reform targets is the timely delivery of advances in research, i.e. early adoption. A number of factors have been demonstrated to cause significant variation in the speed of adoption of innovative healthcare processes and associated improved patient outcomes. Such challenges are pertinent to even the most technologically advanced countries (Chassin, Galvin 1998, Schuster, McGlynn et al. 1998, Kohn 2000, Ferlie, Shortell 2001). Recent advances in sensor technologies and biomarker development have allowed clinical diagnostic testing to be moved closer to the patient and to be used outside of the traditional central laboratory setting, leading to the development of a real need for POCT. The use of POCT is attractive because, theoretically, it permits immediate access to test results for the effective management of patients. It also purports to reduce the Turn Around Time (TAT) for laboratory analysis data to reach the clinician by eliminating some of the pre-analytical requirements, e.g. sample transport, sample preparation (centrifugation, separation, etc.) and post-analytical steps, e.g. data entry and forwarding of the test reports. The need to reduce the TAT of laboratory tests is not new and has been addressed (at least in part) over a number of years by the use of augmentations to central laboratory test regimes such as dedicated pneumatic sampling systems, on-site phlebotomists, satellite laboratories, robotic transport

mechanisms, automated laboratory equipment and computerised information retrieval and reporting systems. Notwithstanding these significant advances, the need for rapid whole-blood and/or urine testing that is close to the patient site is still very real. The development of more sophisticated POCT devices for measuring an increasing range of analytes and the associated enhancement in their sensitivity and selectivity has added additional pressures to have the latest diagnostic systems as widely available as possible, especially outside of major trauma centres (St-Louis 2000, Altieri, Camarca 2001, Yager, Domingo et al. 2008, Willmott, Arrowsmith 2010, Price, St John et al. 2010, St John 2010). In this respect, there is significant debate amongst stakeholders within the healthcare sector with regard to the real value of POCT. Specifically, even though there have been major advances in the diagnostic technologies that underpin POCT device utility, this has not lead to their uptake within the hospital sector at the levels that might have been expected (Loten, Attia et al. 2010).

The nature and relative importance of the various barriers (real and/or perceived) that have been identified as impeding the more widespread adoption of POCT in the clinical environment are not well understood. Current areas of controversy seem to stem from contrasting opinions regarding the clinical value of the data derived from POCT devices and how it is recorded and integrated within the care pathway. At one end of the scale, engineering and related improvements have led to claims that the devices are “fool-proof”, i.e. they can be used without the need for device specific quality measures or structured training. At the other end, there is a strongly held belief that the quality control requirements for data emanating from POCT devices should be exactly the same as that required for central laboratory equipment (Tirimacco, Tate et al. 2010). This range of opinion is not limited to the quality control in POCT but rather covers all areas where a direct comparison can be made between POCT and Central Laboratory Testing (CLT) services that have become synonymous with barriers to adoption of POCT.

As might be expected, the prevalence of published works that use the term “point-of-care testing” as a key search term is high, e.g. the Medline bibliographic database returned 1816 results. Interestingly, 1688 of these 1816 records (93%) were published from 2000 until 2015, with the remainder published between 1991 and 1999. Hence, increased research has been undertaken within the subject area in recent years as health services globally have placed an increasing focus on improving the quality of patient care. In this respect, many articles that focus on POCT speak of the advantages which are possible to achieve with these near patient technologies and the great potential of such systems to enhance healthcare. Whereas a significant number of the published works consider the barriers to the implementation of POCT, few provide suggestions as to how these can be overcome (or indeed avoided). Clearly, to provide solutions to enable the effective clinical implementation of POCT, it is necessary to first

fully understand the nature of the barriers concerned. A key task in this regard is the collation of specific concerns raised by experts in the field. It is therefore the objective of this study to identify, categorise and critically evaluate the known barriers to clinical implementation of POCT through a detailed assessment of relevant literature on the topic in the period 2000 to 2015. It is noted that in a review such as this, contrasting opinions may be found especially between clinicians who practice within different healthcare systems (e.g. those that operate in the UK, USA and Europe). This is important due to the differences in the healthcare systems and associated variances in regulatory structures as well as the prevailing financial models for reimbursement. Therefore, this literature review provides an overview of the various barriers to adoption of POCT within the hospital-based clinical environment, without focusing on any specific healthcare system in particular.

3.2 Study Development & Design

An expansion in the volume and types of information that have been published on POCT in recent years, together with the increasing complexity of interrelated branches of the associated knowledge base, spanning biomarkers and microfluidics to health economics and social science, dictates the need for a systematic search approach and a structured appraisal of previously published research (Taylor 2003). Hence, the methodology employed here has been adapted from that used for systematic review of healthcare interventions (Higgins, Green 2011) as follows:

- Definition of the search question(s).
- Construction of the search formula.
- Specification of inclusion/exclusion criteria.
- Identification of relevant bibliographic databases and associated search engines.
- Operation of search formula on selected databases and search engines and the application of the inclusion/exclusion criteria to filter results.
- Supplementary searches undertaken based on reference lists from all of the literature obtained.

Hence, barriers to the adoption of POCT in clinical practice form the basis of the central search question. Identification and categorisation of these issues is then the first step in the process of understanding their origin (real or perceived). Whereas search terms should be focused in order to identify specific barriers and avoid the capture of superfluous information, they should still be broad enough in scope to attain all of the relevant published data. To this end, the search process employed here was based on that suggested by Taylor (Taylor 2003) and incorporates standard Boolean algebra to convert the search question into targeted concept groups. The

number of terms contained within the concept groups was “fine-tuned” by performing trial searches on some relevant bibliographic databases in order to gauge the levels of relevant literature items being returned from the search process. The concept groups devised in this way generated the following core search formula:

(barrier OR obstacle OR impediment OR disadvantage OR prevention OR problem OR issue)

AND

(adoption OR uptake OR acceptance OR usage OR approval OR utilisation OR utilization OR success)

AND

("point of care" OR poct OR "near patient" OR npt)

AND

(technology OR device OR machine OR instrument OR apparatus)

Importantly, this formula was utilised to search the entire text of the published papers within the selected databases.

For the purposes of this study, POCT refers to any assay or diagnostic test performed outside the central laboratory in a hospital (excluding radiology). Inclusion/exclusion criteria were used to identify relevant literature sources and to qualify the associated information within the search results returned. To be included in the study, papers had to focus on diagnostic POCT used within the clinical environment and so any articles focusing specifically on home use and/or self-testing have been omitted, along with any literature with a specific emphasis on such testing performed within the remit of primary care. Papers reporting the use of non-diagnostic POCT devices, e.g. Personal Digital Assistants (PDAs) or other phone or tablet-based decision support systems providing a link to clinical knowledge bases were also omitted. All of the papers selected were limited to those published in the English language. Furthermore, to be included papers must have been published in the period January 2000 to December 2015 which reflects the period when there was a significant expansion in the published literature produced within the subject area.

This search protocol was then applied to a set of 6 electronic databases, namely; Medline, Compendex, Inspec, Web of Science, Technology Research Database and PubMed. In order to evaluate the usefulness of each database, the sensitivity and precision of the searches were calculated. The sensitivity of a particular database search to returning relevant information was calculated by taking the number of relevant articles by an individual database and dividing it by the total number of relevant articles obtained from all 6 database searches (after removal of

duplicates). The higher the sensitivity of a database search, the larger the quantity of relevant literature returned. Likewise, the precision of each database was determined as a measure of relevant articles returned divided by the total number of hits obtained from that particular database search. As such, this represents an evaluation of the ability of a database to avoid returning irrelevant items and is essentially a measure of the predictive value of a particular database search. Although a higher sensitivity is more beneficial, ideally a balance between sensitivity and precision is required in order to return a more manageable set of search results for assessment.

The searches of the main databases were supplemented using the "Google Scholar" web-based search engine. Due to the more simplistic nature of this web interface (and its associated limitations) the search formula was modified such that only the first concept group was used to access papers, as follows:

> *(barrier OR obstacle OR impediment OR disadvantage OR prevention OR problem OR issue)*
>
> *AND*
>
> *"point of care"*
>
> **Note: This formula was applied to search only the titles of articles.*

Once the searches of 6 electronic databases was carried out and relevant papers identified, full text copies of each were obtained for systematic review within the study. In order to supplement the review further, the reference lists provided within each of the articles was reviewed in full to identify other valuable papers within the field that may have been missed by the search process. The references cited within the latter group of publications were also searched as a final phase of the search process.

3.3 Study Results

Outputs from the structured searches carried out on each of the 6 electronic bibliographic databases and the Google Scholar web search engine are shown in Table 3.1 in respect of number of hits, relevance of hits, sensitivity and precision. Overall, the total number of relevant hits returned from the combined searches was 31 after the removal of duplicates.

In addition, 24 papers of significant value were identified from the reference lists of the 31 papers returned from the database searches that met the inclusion criteria obtainable. A further 10 publications were found in the reference lists of this additional set of papers, giving a final

total of 65 papers meeting the inclusion criteria. After removal of 2 papers for which a full text copy could not be sourced, 63 key articles were subsequently assessed in detail.

As indicated in Table 3.1, in terms of sensitivity and precision, 3 of the databases searched performed well in the study, while the other 3 performed quite poorly. Medline demonstrated the highest level of sensitivity, returning 17 of the 31 (55%) relevant hits from the initial search, which translated into a precision of 8%. Web of Science also provided a precision of 8%, however, it had a lower sensitivity of 35% by comparison. PubMed was next best in terms of sensitivity, providing a value of 23% and a precision of 7%. The inclusion of Medline, Web of Science and PubMed in the top 3 is perhaps unsurprising given their respective focus on medicine and life sciences as opposed to the emphasis on engineering, science and technology in the other 3 databases; Compendex, Inspec and the Technology Research Database. It should also be noted there was a significant degree of overlap between the higher performing databases.

Table 3.1 – Literature review search sensitivity and precision results by database.

Database	Total Hits	Relevant Hits	Sensitivity	Precision
Medline	218	18	55%	8%
Compendex	209	2	6%	1%
Inspec	83	4	13%	5%
Web of Science	136	11	35%	8%
Technology Research Database	83	1	3%	1%
PubMed	99	7	23%	7%
Google Scholar	53	7	23%	13%

Based on a detailed assessment of the topics reported in each the 63 articles utilised in the study, 4 distinct categories of barrier to clinical adoption of POCT devices were identified, as follows:

- Economic issues.
- Quality assurance & regulatory issues.
- Device performance & data management issues.
- Staff & operational issues.

The allocation of each of the articles to these categories is provided in Table 3.2.

Table 3.2 – Categorisation of articles assessed within the literature review process by barrier to POCT adoption.

Barrier Category	References	Total	% of Assessed Articles
Economic issues.	(Zydron, Woodworth et al. 2011, St-Louis 2000, Vashist, Luppa et al. 2015, Pearson 2006, Nichols 2003, Nichols 2005, Rajendran, Rayman 2014, Migliore, Ratti et al. 2009, Price 2001, Huckle 2006, Melo, Clark et al. 2011, Price 2002, Huckle 2008, Foster, Despotis et al. 2001, Huckle 2010, McNerney, Daley 2011, Hortin 2005, Crook 2000, Creed 2001, FitzGibbon, Huckle et al. 2010b, Louie, Tang et al. 2000, FitzGibbon, Huckle et al. 2010a, FitzGibbon, Brown et al. 2007, Halpern 2000, Linder 2007, Boonlert, Lolekha et al. 2003, FitzGibbon, Huckle et al. 2011, Fermann, Suyama 2002, Lewandrowski, Flood et al. 2008, Gregory, Lewandrowski 2009, Blick 2001, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Goodwin 2008, Lee-Lewandrowski, Lewandrowski 2001, Dhawan, Heetderks et al. 2015, Giuliano, Grant 2002, Freedman 2002, Cvitkovic 2011, Lee, Shin et al. 2011)	40	63%
Quality assurance & regulatory issues.	(St-Louis 2000, Vashist, Luppa et al. 2015, Tantra, van Heeren 2013, Plerhoples, Zwemer et al. 2004, Pearson 2006, O'Kane, McManus et al. 2011, Nichols 2003, Nichols 2005, Rajendran, Rayman 2014, Kiechle, Main 2000, Murray, Fitzmaurice et al. 2004, Price, Kricka 2007, Huckle 2006, Melo, Clark et al. 2011, Meier, Jones 2005, Huckle 2008, Huckle 2010, McNerney,	41	65%

	Daley 2011, Crook 2000, Creed 2001, FitzGibbon, Huckle et al. 2010b, Luppa, Müller et al. 2011, Louie, Tang et al. 2000, FitzGibbon, Huckle et al. 2010a, Briggs, Kimber et al. 2012, FitzGibbon, Brown et al. 2007, Halpern 2000, FitzGibbon, Meenan et al. 2007, Linder 2007, Boonlert, Lolekha et al. 2003, Groves 2005, FitzGibbon, Huckle et al. 2011, Fermann, Suyama 2002, Lewandrowski, Flood et al. 2008, Gregory, Lewandrowski 2009, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Lee-Lewandrowski, Lewandrowski 2001, Giuliano, Grant 2002, Cvitkovic 2011, Lee, Shin et al. 2011)		
Device performance & data management issues.	(Zydron, Woodworth et al. 2011, You, Chung et al. 2013, Swayze, Rich 2012, St-Louis 2000, Vashist, Luppa et al. 2015, Shephard 2011, Sheikholeslam, Pritzker et al. 2011, Perry, Fitzmaurice et al. 2010, Nichols 2003, Knaebel, Irvin et al. 2013, Nichols 2005, Rebel, Rice et al. 2012, Rajendran, Rayman 2014, Kiechle, Main 2000, Murray, Fitzmaurice et al. 2004, Melo, Clark et al. 2011, Meier, Jones 2005, Huckle 2008, Huckle 2010, Crook 2000, Carraro, Plebani 2009, Louie, Tang et al. 2000, FitzGibbon, Huckle et al. 2010, FitzGibbon, Brown et al. 2007, Halpern 2000, Linder 2007, Groves 2005, Fermann, Suyama 2002, Gregory, Lewandrowski 2009, Blick 2001, Goodwin 2008, Lee-Lewandrowski, Lewandrowski 2001, Dewsnap, Mcowan 2006, Cvitkovic 2011)	34	54%
Staff & operational issues.	(Zydron, Woodworth et al. 2011, Pearson 2006, Price, Kricka 2007, Price 2001, Price 2002, Huckle 2008, Foster, Despotis et al. 2001,	18	29%

	Huckle 2010, Crook 2000, FitzGibbon, Brown et al. 2007, Halpern 2000, FitzGibbon, Meenan et al. 2007, FitzGibbon, Huckle et al. 2011, Fermann, Suyama 2002, Blick 2001, Lee-Lewandrowski, Lewandrowski 2001, Giuliano, Grant 2002, Freedman 2002)		
No specific barriers identified.	(Kodogiannis 2013, Kitchen, Kitchen et al. 2012, Myers, Browne 2007)	3	5%

It should be noted that 3 of the 63 papers assessed were categorised as having been identified against no specific barriers to POCT adoption. Despite meeting all the set criteria, these articles tended to focus on the positive impact which the implementation of POCT can bring, rather than on any particular impediments to their adoption within the clinical environment.

Of the 63 articles reviewed, 15 (24%) were produced as an output from original research that provides results from a survey or a clinical study while the remaining 48 (76%) were either expert opinion-based papers or review articles. Overall 59 (94%) of the sources were journal articles, 4 of which were published in online only journals and, in total, 58 were published in peer reviewed journals. Of the remainder, 2 were book chapters and 2 were sourced from published conference proceedings. For the purposes of this investigation the original research, expert opinion pieces and review articles have all been taken as being of equal importance without any application of a "hierarchy of evidence". While the value of more rigorous research methodologies and/or structures is recognised here, the rationale for this was to take all available evidence and systematically assess the entire body of work available in order to develop a pool of information upon which to base a primary study to validate such. A lack of primary research investigating the barriers to adoption of POCT exists, which is a driving factor in the development of this research, hence making it difficult to differentiate existing work based on a hierarchical level of importance. However, for completeness, a brief discussion of the findings of the original research subset has been included.

3.4 Discussion

Each of the categories of barrier to adoption of POCT defined herein was assessed with regard to the key issues considered within the relevant published works as outlined below.

3.4.1 Economic Issues

The set of 40 articles reviewed in respect to economic issues indicated that, at varying levels, circumstances of this nature were directly impacting on the adoption of POCT in an adverse manner within the clinical environment. Whereas 8 of these works alluded to economic

impediments in a non-specific sense, the remaining articles were found to focus on 5 specific issues:

1. The cost per test of POCT is higher than that of traditional CLT.

When considered on a simple test-by-test basis, traditional batch testing methods offered by central laboratory facilities are generally found to be less expensive than POCT (St-Louis 2000, Vashist, Luppa et al. 2015, Price 2001, Huckle 2006, Price 2002, Huckle 2008, Crook 2000, Creed 2001, FitzGibbon, Huckle et al. 2010, Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Goodwin 2008, Cvitkovic 2011, Lee, Shin et al. 2011). In large measure this is deemed to be due to the disposable nature of POCT technologies and how this affects consumable costs. For example, St-Louis (St-Louis 2000) reports evidence that POCT costs for glucose and for blood gas/electrolyte testing have been calculated to be 1.1 to 4.6 times that of the equivalent CLT. 15 of the 63 assessed articles (24%) made reference to this particular issue which indicates its level of significance. Hence, for many stakeholders within the healthcare sector, a simple head-to-head cost analysis indicates a higher per test cost of POCT and is therefore seen as a major issue in the justification of their adoption. A previous survey of clinicians and nurses found that 80% of respondents either "strongly agreed" or "agreed" that the cost per test of point-of-care devices acted as a barrier to the adoption of such devices for cardiac marker measurement (FitzGibbon, Huckle et al. 2010). In the same investigation, a survey of laboratory scientists found that 65% of respondents either "strongly agreed" or "agreed" with the same statement. Conversely, 7 of the assessed articles (St-Louis 2000, Creed 2001, Goodwin 2008, Huckle 2008, Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003) allude to the fact that this type of simple financial analysis is not a sufficient means for assessment of the true value of a POCT system. It is argued that apparent gains, such as improved quality of care for patients, reduced length-of-stay in hospitals, improved test TATs, etc. are not adequately represented in such an approach.

2. The cost-effectiveness of a POCT system is difficult to gauge and cost comparison studies against traditional CLT methods are complex.

When considering the potential gains that are obtainable through the use of POCT technologies, a significant difficulty lies in placing a specific financial value on the benefits which may be realised over a longer time scale (Fermann, Suyama 2002, Goodwin 2008, Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Lee-Lewandrowski, Lewandrowski 2001). In particular, overall economic savings from POCT are not as immediately apparent as those of laboratory-based batch testing and therefore performing cost comparisons can be challenging. Furthermore, Hortin (Hortin 2005) indicates that

perspective plays a major role in determining the cost-effectiveness of POCT and is specifically dependant on the opinion of the representation of labour costs and the allocation of personnel time as a result of the use of POCT. Conducting an adequate cost-effectiveness study on a POCT system is complex (Zydron, Woodworth et al. 2011, St-Louis 2000, Rajendran, Rayman 2014, Foster, Despotis et al. 2001) and historically a wide range of evaluation methods have been used in an attempt to accomplish this which has made any direct comparison of results difficult (Giuliano, Grant 2002). It is also stated that, in most instances, the primary cost justification for POCT is based on the assumption that "time is money" which makes the application of precise cost-effectiveness studies difficult (Foster, Despotis et al. 2001). Debate is growing with respect to the cost-effectiveness of POCT and arguments exist on either side with some being of the opinion that it is more expensive than CLT, while others are of the belief that it is cheaper than CLT. Some of the latter opinion suggests that it is more expensive but brings other benefits such as reduced patient length of stay (Louie, Tang et al. 2000).

Of the articles assessed, 6 also indicate that outcome measures and the costs of POCT are often location-specific which adds to the difficulties in making comparisons across multiple sites (Zydron, Woodworth et al. 2011, St-Louis 2000, Foster, Despotis et al. 2001, Crook 2000, Lee-Lewandrowski, Lewandrowski 2001, Nichols 2005). Therefore, it is difficult for an organisation to follow any sort of standardised approach in justifying a POCT system, as due to a lack of reliable outcome data, no such robust approach to their assessment exists.

3. The initial costs of implementing a POCT system can be high.

There are considerable direct and indirect costs associated with implementing any new system within a clinical environment, and in this respect a POCT system is no different (Lee-Lewandrowski, Lewandrowski 2009, Zydron, Woodworth et al. 2011). In times of reduced budgets across the healthcare sector, the difficulties in justifying such a system become even greater. It has been stated in the relevant literature that if the central laboratory is unable to carry out tests away from their normal environment, then the implementation of a POCT system almost certainly will be more expensive than the cost of performing more tests in a central facility (Foster, Despotis et al. 2001). Even if certain tests currently offered by central services were to be removed there would still need to be a period of overlap when both standard CLT and POCT are being carried out which will then incur increased costs, at least on a temporary basis.

In the case of POCT, direct costs include the purchase or lease of new instruments along with consumables such as the disposable test substrates and reagents, etc., while indirect costs relate to training of staff, quality assurance, etc. The increased complexity of devices and their multiplex operations can lead to extensive (and expensive) indirect costs such as training and

competency assessment (Vashist, Luppa et al. 2015). However, other operational aspects, such as information technology (IT) connectivity, also need to be taken into consideration when calculating the true cost of implementation (Nichols 2003, Boonlert, Lolekha et al. 2003, Blick 2001). For example, it is estimated that the IT connectivity costs for cardiac marker POCT devices could be as high as £20,000 per centre (FitzGibbon, Huckle et al. 2010).

A further issue resulting from POCT implementation is that of increased testing, i.e. their availability may lead to a rise in the number of tests undertaken due to the technology being more accessible. Clearly, implementing a new diagnostic regime without overwhelming evidence as to the benefits to be realised makes it difficult to convince stakeholders that such a system will eventually deliver a more cost-effective provision, especially if their introduction will increase the amount of diagnostic testing taking place.

4. The allocation of budgets for POCT is not appropriate.

There are indications within the articles assessed here that, in general, POCT does not attract specific budget allocations and it is therefore suggested that spend profiles within the relevant healthcare budgets need to be adapted in order to take this into account (Huckle 2006, Huckle 2008, Creed 2001, FitzGibbon, Huckle et al. 2011). This problem is most prevalent in areas of so-called traditional “silo budgeting” where separate departments receive separate budgets. In many of the NHS trusts within the UK, the clinical pathology is still centrally funded and receives the same remittance, irrespective of workload (Creed 2001). This in effect means that a clinical specialty which takes on responsibility for aspects of its own pathology workload by adopting POCT receives no central funding but has to bear the cost pressures from existing departmental budget allocations. If the use of POCT by one department deducts from the budget of another, this could lead to an efficient use of available resources and services. It is therefore suggested that a payment model based on the patient care pathway might be a way to maximise the benefits of timely and accurate diagnosis.

5. Reimbursement is a major hurdle to POCT implementation.

Reimbursement is described in the literature reviewed here as a major barrier to POCT adoption (FitzGibbon, Huckle et al. 2011, FitzGibbon, Huckle et al. 2010, Gregory, Lewandrowski 2009, Blick 2001, Vashist, Luppa et al. 2015, Huckle 2006, Melo, Clark et al. 2011, Huckle 2010). Essentially the problem lies with determining who pays for the test to be carried out and this varies from country to country. It would seem that political control of reimbursement has prevented significant growth in the adoption of POCT, especially within the European healthcare structures (Huckle 2006). In some European countries, such as France and Spain, limitations prevent doctors from performing any form of diagnostic tests which adds a further dimension

to an already complex problem. There are a limited number of products that can be reimbursed, but these vary widely between the USA and Europe and even more so within the individual European countries. Political structures have been under pressure to reduce healthcare spending due to the global economic crisis and so the reimbursement of POCT products, that may appear to be more expensive than CLT, is difficult to attain. There has been a reduction in growth of POCT uptake even in the leading markets such as Germany and the USA.

Depending on the reimbursement structure in operation, POCT may significantly affect the revenue generated by clinician consultation fees. For example, in some European countries a clinician will have an initial consultation with a patient after which they will send off the sample for laboratory analysis with the results then presented at a subsequent consultation. This scenario commonly results in the payment of 2 fees as well as the cost of the test(s) to the clinician (Huckle 2010). In theory, the implementation of POCT can result in the loss of the second consultation fee which is obviously a major issue with regard to the expected payment structure. With regard to the associated payment for POCT testing, it is suggested how the use of diagnostic related groups (DRGs) could control the utilisation of POCT and avoid unnecessary testing, by inclusion of the cost of testing within a flat rate for the entire episode of care regardless of how many tests are performed (Gregory, Lewandrowski 2009).

Although not categorised within the 5 areas of primary focus for economic considerations as outlined above, McNerney and Daley make an interesting point that is worth highlighting. They suggest that there has been a lack of investment in diagnostic tests, including POCT, due to the fact that developing new drugs can yield a much more attractive commercial economic return. As a consequence of this lack of investment, problems identified in the past as being addressable via POCT are not being overcome and may still persist in current devices thereby limiting their utility and adoption (McNerney, Daley 2011).

Clearly, impediments of an economic nature have been recognised as being highly relevant within this systematic literature review. Specifically, the higher cost per test of POCT and the difficulties in performing adequate cost-benefit and/or cost-effectiveness studies on their utility have been found to be of upmost significance. Clearly, these 2 issues are interlinked. A successful solution to determining the value of the benefits obtainable through the use of POCT, i.e. improved quality of care, quicker intervention, reduced lengths of hospital stay, fewer admissions, etc. would allow an accurate calculation of the real cost-benefit/cost-effectiveness of such systems, hence being able to justify any extra expense on a per test basis.

In terms of publication frequency on economic issues, a slight clustering (15 of 40 articles) was identified in the period 2008 to 2011. It is suggested that this may have been in response to the

global economic recession which was causing significant reductions in public sector budgets at this time.

3.4.2 Quality Assurance & Regulatory Issues

Impediments relating to quality assurance and regulatory requirements were also frequently recognised in the literature review study, being highlighted in 41 of the assessed articles. Of these, 11 made reference to quality assurance and regulatory issues as posing a significant challenge to POCT adoption in a general manner, with no focus on any particular area. Within the remainder, the following 3 issues were highlighted in a more precise fashion:

1. Device operation by untrained or non-competent staff.

The dispersion of POCT devices throughout all areas of a healthcare system gives rise to opportunities for untrained or non-competent staff to use the devices. This can lead to a disregard for certain quality assurance steps and procedures, including essential aspects of quality control. The high dependence on operator competency in terms of test quality of POCT escalates this issue, which has been highlighted as a specific area of concern for POCT and is therefore seen as a barrier for its effective clinical adoption (Vashist, Luppa et al. 2015, Pearson 2006, O'Kane, McManus et al. 2011, Nichols 2003, Rajendran, Rayman 2014, Kiechle, Main 2000, Meier, Jones 2005, Crook 2000, Creed 2001, Luppa, Müller et al. 2011, Louie, Tang et al. 2000, Briggs, Kimber et al. 2012, Halpern 2000, Fermann, Suyama 2002, Lee-Lewandrowski, Lewandrowski 2009, Giuliano, Grant 2002, Huckle 2006).

Quality issues can occur due to user errors such as the inappropriate storage of reagents and the incorrect collection of blood specimens (Fermann, Suyama 2002, Nichols 2005). Furthermore, devices that have been incorrectly calibrated by non-competent staff have been known to affect the results from POCT devices in an adverse manner (Fermann, Suyama 2002, FitzGibbon, Meenan et al. 2007). There are indications that a lack of training, poor standardisation in obtaining blood samples and insufficient internal/external quality assessment are the main reasons for the underperformance of POCT (Briggs, Kimber et al. 2012).

It should be noted that POCT devices have been found to be more challenging regarding quality control monitoring in comparison to traditional CLT methods. A survey of clinicians (including nurses) and clinical bioscientists has found that the majority of both clinical groups “disagreed” or “strongly disagreed” that POCT devices reduced the amount of quality monitoring required for cardiac marker measurement (FitzGibbon, Huckle et al. 2010). This highlights the need for appropriate training of POCT operators in order to ensure that adequate quality assurance procedures are in place along with tighter control over who can perform POCT and has access to such devices.

2. Complex regulatory requirements.

Regulations for accreditation of analytical testing methods are complex with regard to POCT and a number of articles have referred to the burden imposed by such requirements, implying that they inhibit its implementation within clinical institutions (Cvitkovic 2011, Plerhoples, Zwemer et al. 2004, Creed 2001, Linder 2007, Groves 2005, Gregory, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Lee-Lewandrowski, Lewandrowski 2001). For example, reference is made to the rigorous reporting and documentation requirements that can make POCT difficult to maintain in some cases (Plerhoples, Zwemer et al. 2004). Furthermore, it has been found that, at times, regulations written for traditional CLT instrumentation are blindly applied to modern POCT devices (Groves 2005). This is an inappropriate approach which poses significant challenges to the non-laboratory operators of the devices.

Testing and accreditation regulations are intended to ensure certain quality assurance procedures are adhered to, however, a notable indication in the relevant literature base states that it appears that, in the past, regulations in the UK, whilst managed by Chemical Pathology Accreditation (CPA), attempted to stop the trend towards the decentralisation of laboratories by restricting the type and size of laboratory that could become accredited (Creed 2001). Instead of using accreditation to improve quality, Creed is of the opinion that the regulators endeavoured to “move the goalposts” by enforcing overly complex regulations in order to safeguard the future of the central laboratory. However, the CPA is now absorbed and managed by the United Kingdom Accreditation Service (UKAS), with laboratories now assessed to ISO 15189, the recognised international standard for medical laboratories.

Additionally, there can be further problems with the process by which new requirements are established. For example, changing regulatory requirements is a challenge with regard to managing a POCT program (Gregory, Lewandrowski 2009). Maintaining compliance with an evolving set of regulatory requirements can be an even more difficult task. There have also been indications of the challenges in maintaining regulatory compliance for a POCT system (Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Corboy et al. 2003), especially in larger institutions. These issues tend to stem from the dispersed nature of the devices, making them more difficult to control and regulate than those in a centralised laboratory system.

The regulatory control requirements of POCT products and their use will depend on the where they are marketed. In Europe, regulation lies specifically within the Diagnostics Directive (a sub-section of the Medical Devices Directive), while in the US the product must either meet Food & Drug Administration (FDA) approval standards or be compliant with the Clinical Laboratory Improvement Act (CLIA) which allows diagnostic products to be used in approved laboratory facilities (Huckle 2010). This approach establishes the suitability of a facility to perform POCT

activities and also assesses the suitability of a POCT product for use at such a facility. Regulations imposed by CLIA divide POCT into 2 categories; waived and non-waived tests. Waived tests are defined as tests that use simple but accurate methods with either a small probability of error or that pose no significant risk of harm if they are performed incorrectly. The non-waived category of tests includes both moderate and more highly complex sub-types (Lee-Lewandrowski, Lewandrowski 2001). Utilising this regulatory approach can, however, result in further complexities. A POCT analyser may be classed as being waived for testing a certain group of analytes and the rapid turnaround of results may increase the desire of clinicians to have additional testing available at the patient site. Moreover, adding a further analyte to the test menu for this analyser may promote its use to the non-waived category, which then requires more significant personnel qualifications for the user, advanced quality control requirements and other function testing (Cvitkovic 2011).

3. Product qualification.

There have also been indications that regulations relating to product qualification/approval for POCT devices have acted as a barrier to their development and clinical uptake (Tantra, van Heeren 2013, Huckle 2008, McNerney, Daley 2011). Indications suggest that the complexity of the registration processes discourages economic investment in the development of POCT devices (McNerney, Daley 2011). Clearly, a lack of investment in the area directly impacts upon the potential for the more widespread implementation of POCT.

Concerns regarding quality assurance and regulatory requirements have been found to be highly relevant by this literature review study. In particular, device operation by untrained/non-competent staff was found to be significant, with quality assurance/control aspects being pertinent in 21 of the 63 assessed articles (33%). Furthermore, overly complex regulatory requirements for the accreditation of POCT have been identified as a significant barrier to their more widespread uptake within the clinical environment. A major difficulty in controlling the use of POCT is deemed to be due to the dispersed nature of the devices. Measures have been taken in the past to try and overcome this issue, such as the requirement for authorisation codes for use for such devices. However, this proved to be an inadequate solution in most cases, for instance there are notified problems with clinicians forgetting their assigned codes, which directly affected intervention times in the care of critically ill patients. The perceived issue of overly complex regulatory issues may well be true for POCT. Operators who are not from a laboratory background may find the regulations more difficult to comply with compared to those with more experience in the traditional methods of analytical testing. Therefore, the clinical specialty of the user is an important consideration in this regard.

The frequency of publications across the review period that address quality assurance and regulatory aspects of POCT remained fairly constant, indicating that all of these issues are of on-going concern.

3.4.3 Device Performance & Data Management Issues

Device performance and data management issues were cited as acting as barriers to the adoption of POCT within the clinical environment in 34 of the assessed articles. There were 3 main areas of focus within this category:

1. Reduced analytical performance in comparison to centralised laboratory testing.

19 articles made reference to poor analytical performance of POCT devices as being a barrier to their adoption (Zydron, Woodworth et al. 2011, You, Chung et al. 2013, St-Louis 2000, Vashist, Luppa et al. 2015, Shephard 2011, Sheikholeslam, Pritzker et al. 2011, Perry, Fitzmaurice et al. 2010, Knaebel, Irvin et al. 2013, Nichols 2005, Rebel, Rice et al. 2012, Rajendran, Rayman 2014, Murray, Fitzmaurice et al. 2004, Melo, Clark et al. 2011, Huckle 2008, Huckle 2010, Carraro, Plebani 2009, Louie, Tang et al. 2000, FitzGibbon, Brown et al. 2007, Goodwin 2008), including issues with their specificity, sensitivity and precision. The technological performance of POCT devices is a topic of much ongoing debate. This lack of performance, whether real or perceived, has been cited in 30% of the assessed articles within this review and so must be considered as a significant barrier to POCT adoption. As an example, there are indications within the literature reviewed here alluding to the poor correlation between POCT and CLT results for International Normalised Ratio (INR) testing (a measurement of blood coagulation in the circulatory system often associated with monitoring the effectiveness of anticoagulation therapy) (Murray, Fitzmaurice et al. 2004, Perry, Fitzmaurice et al. 2010). Furthermore, there are references to the variable performance and low reproducibility of POCT devices, including evidence from a study of 8 POCT instruments (7 of which were National Glycohemoglobin Standardisation Program (NGSP) certified), 6 of which were found to have produced clinically unacceptable reproducibility (St-Louis 2000, Melo, Clark et al. 2011).

Poor analytical performance can lead to serious problems with “false negatives” (and “false positives”) within test results. A survey of clinical bioscientists, clinicians and nursing staff found this to be a major concern (FitzGibbon, Brown et al. 2007). In particular, “false negatives” can result in a lack of timely medical intervention which can have disastrous consequences for some patients.

2. Connectivity and data management problems.

Data management issues often stem from a lack of adequate connectivity capabilities. 15 articles assessed in this review have highlighted the generally poor connectivity of POCT devices

(Swayze, Rich 2012, St-Louis 2000, Vashist, Luppa et al. 2015, Rajendran, Rayman 2014, Kiechle, Main 2000, Meier, Jones 2005, Huckle 2010, Carraro, Plebani 2009, FitzGibbon, Huckle et al. 2010, Halpern 2000, Gregory, Lewandrowski 2009, Blick 2001, Goodwin 2008, Lee-Lewandrowski, Lewandrowski 2001, Cvitkovic 2011). It is accepted that this issue is not specific to POCT devices and may apply to any dispersed system within the healthcare sector where IT connectivity is crucial. However, this implication has been widely recognised by champions of POCT in healthcare. For example, the work of the Connective Industry Consortium (CIC), first convened in 1999, was highlighted in the reviewed literature with respect to creating connectivity standards for POCT devices (Cvitkovic 2011). However, some 18 years later, POCT devices are often found not to be compliant with these standards, either due to a lack of updating original submissions or the manufacturer's unwillingness to embrace the fundamental requirements of the CIC standards. Connectivity has been said to be at the core of POCT "growing pains" (St-Louis 2000). The effects of a lack of adequate connectivity are most readily seen in large institutions or within multi-site systems where a dispersed set of devices can create a number of data management issues (Nichols 2003, Crook 2000, Halpern 2000, Groves 2005, Fermann, Suyama 2002).

Poor connectivity of POCT devices may lead to a number of subsequent problems. For example, a lack of a direct link between POCT results and the patient record system can result in the duplication of tests due to clinicians being unable to access the most up-to-date data sets (Crook 2000, Groves 2005). This has the associated effect of increasing the overall cost of a diagnostic testing system which is already under scrutiny with regard to the additional expenditure which it may incur. Moreover, POCT results are normally presented in a simplistic manner, which often must be manually recorded by the operator due to the lack of adequate connectivity. Issues can then occur with the transposition of the values attained from POCT test results due to the limited amount of data that can be stored on them (Nichols 2005). A POCT system, due to its decentralised nature, relies on having adequate IT connectivity in order to perform effectively. The problems identified here indicate the significance of this issue in terms of impeding the utilisation of POCT to its full potential.

3. Poor usability of devices.

This review has uncovered a number of usability issues associated with POCT devices. Firstly, a lack of standardisation can cause confusion for operators. It is stated that devices that are similar in design may operate differently or have different features. Since clinical staff commonly rotate between various sites, this issue can become a significant problem for those who are required to operate a "similar" device in different environments (Swayze, Rich 2012). Calibration and reference sources for POCT devices have also been indicated as issues (Crook

2000, Goodwin 2008). Clearly, a comparison of results from different devices on the same site will be difficult if they have been calibrated with different reference solutions.

Furthermore, inadequate clarity of the output of POCT results and poor user instructions have also been cited as factors that contribute to adverse events. It has been found that ease-of-use is an issue that still needs to be addressed with regard to POCT implementation (Linder 2007). This particular aspect is seen as a significant impediment to the adoption of such devices as their performance is much more dependent on the operator compared to that of traditional CLT (Nichols 2005).

Adverse incidents caused by poor build quality of POCT devices and associated test cartridges have been reported. Evidence has been found in the literature reviewed here of a study in which there were 4 incidents of the glass capillary tube fracturing in a POCT HIV testing kit (Dewsnap, Mcowan 2006). Although not a frequently occurring problem, it is important to note that portable instruments such as POCT devices must be of an adequately robust nature.

The significance of a real or perceived reduction in analytical performance of POCT in comparison to CLT is apparent by its prevalence in the articles assessed in this study, with this issue having been cited in 19 of the 63 (30%) reviewed. Clearly, a clinician will not perform a new type of analytical test if they see it as being inferior to an existing method and hence evidence of efficacy is essential. Furthermore, connectivity and data management problems have also been identified as being highly significant. Again, this issue may emanate from the dispersed nature of POCT systems and must be managed accordingly to accommodate their successful implementation.

The frequency of publications on device performance and data management related matters remained fairly constant across the review period, with the exception of a slight increase in 2010-2011, 8 of the 34 articles pertaining to this category of barrier were published across these 2 years. The majority of these papers indicated some focus on reduced analytical performance, suggesting a more intense scrutiny on the performance of POCT devices. It is noted that, the capabilities of the devices in the period question were likely to be superior to earlier generations of the same instruments, however, with technological advancements also comes increased user expectation.

3.4.4 Staffing & Operational Issues

A total of 18 articles indicated that staffing and operational issues have acted as barriers to the adoption of POCT within the clinical environment. The nature of the barriers within this category focus on 6 main issues:

1. Reduced levels of staff satisfaction and increased friction between staff groups.

Levels of staff satisfaction can be directly affected by the implementation of a POCT system, according to the findings of this review study. Several papers indicate how users experience an increased work-load when operating POCT devices (Zydron, Woodworth et al. 2011, Fermann, Suyama 2002, Giuliano, Grant 2002). Furthermore, it has been suggested that laboratory staff may fear a degradation of their role or ultimately loss of employment due to the introduction of POCT (Fermann, Suyama 2002).

A number of the articles assessed also suggest that relations between clinicians and laboratory staff can be affected due to the implementation of a POCT system (Fermann, Suyama 2002, FitzGibbon, Brown et al. 2007, Halpern 2000, FitzGibbon, Meenan et al. 2007, Blick 2001). There are suggestions that these concerns mostly emanate from the removal of the vital role of quality assurance and test-result verification when not performed in the central laboratory environment, rather than issues of ownership *per se* (FitzGibbon, Meenan et al. 2007). However, the implementation of POCT can lead to tension in the hospital environment with regard to "turf" battles, political in nature, in which one clinical group sees its dominance and expertise being invaded by another group that is performing similar functions with what is assumed to be less training and at (supposed) lower cost (Halpern 2000, Blick 2001). Satisfaction levels of users can also be affected by the confidence that they have with the system being used.

Various measures have been taken in order to allay concerns regarding the technical and analytical performance of POCT. For example, the National Institute of Health (NIH) in the USA has funded 4 POCT technology centres and the National Institute of Clinical Excellence (NICE) in the UK has set up a diagnostics assessment group (Huckle 2010). Greater acceptance of POCT by central laboratory staff has allowed for their involvement in ensuring the quality assurance of instruments and the attendant results. Hence, progress on addressing this particular barrier to hospital-based clinical adoption of POCT has been more positive in recent years.

2. Resistance of the central laboratory to pass control of testing to others.

Several articles have cited resistance of the central laboratory staff to release control of testing to others as a barrier to the adoption of POCT (Fermann, Suyama 2002, Huckle 2008, Halpern 2000). This desire to retain control generally originates from concerns regarding the quality assurance of test data, rather than from fears over any loss of job responsibility or professional distinction. There are indications that the central laboratory is not interested in sharing administrative or operational control of laboratory testing with a clinician group that is not formally trained (Halpern 2000). Furthermore, it is suggested that there is a reluctance of central analytical facilities to accept that sufficient technical and analytical performance can now

be achieved using POCT devices (Huckle 2010). The central laboratory is unlikely to be content to release control over testing until they are fully satisfied that this is the case and that suitable training regimes are mandatory.

3. Inappropriate use of POCT.

This study has also found that inappropriate use of POCT has acted as a barrier to its wider implementation. The availability of tests may cause an increase in inappropriate testing (Crook 2000). Using POCT devices simply because they are available and easily accessible (and not because they are the most appropriate option) significantly increases testing costs, which may cause the POCT system to be economically unviable.

4. Alterations to clinical care pathways.

Difficulties surrounding operational changes needed with regard to established clinical care pathways and role of the central laboratory in supporting them have been cited as issues in a number of the articles assessed in this review study (Zydron, Woodworth et al. 2011, Price, Kricka 2007, Huckle 2008, Huckle 2010, FitzGibbon, Huckle et al. 2011, Lee-Lewandrowski, Lewandrowski 2001). It has been stated within the reviewed literature that the need to change current practices to realise clinical benefits is one of the 4 main challenges for POCT implementation (Price, Kricka 2007). This proposition is reinforced in 2 related pieces of literature by Price (Price 2001, Price 2002) which suggest that POCT will only become widely used if the potential savings promised can actually (and demonstrably) be realised. Moreover, these benefits will only be delivered if the advantage of POCT delivery is built into a new clinical protocol in which the results are speedily and efficiently acted upon. Clearly, simply placing POCT devices into the current clinical pathways and workflow will not provide an efficient solution. For POCT to deliver both a clinical and economic benefit, the information provided by the test must result in either more rapid treatment or discharge, or otherwise lead to a positive alteration in the care provided. This is not always the case, for example in the assessment of chest pain using cardiac markers, it has been reported that while rigidly applying a rapid cardiac rule out protocol based on POCT data would greatly reduce admissions, in practice clinical judgment and other diagnostic information typically take precedent (Boyd, Dixon et al. 2012, Dixon, Eatock et al. 2009).

The literature reviewed describes how technology that causes disruptive complex workflow changes creates barriers to its adoption (Zydron, Woodworth et al. 2011). Such changes are required in order to fully realise the benefits of POCT and so any disruption must be managed to minimise any resistance to adoption. Difficulties exist when attempting to implement a POCT system in an institution with an existing fully functional central laboratory. For example, as

pneumatic tube systems for sample transport are often already connected to acute care areas, then the central laboratory is effectively close in proximity to these areas. Hence, access to the central laboratory resources is often maintained alongside the POCT (and commonly overlap with them) thereby nullifying many potential benefits of the new systems (Foster, Despotis et al. 2001).

5. Management structure and clinical governance.

With regard to the management of POCT, 3 papers refer specifically to the type of structure that is required in order for such a system to run efficiently (Zydron, Woodworth et al. 2011, Pearson 2006, Price, Kricka 2007). These publications all refer to "silo management" thinking that has been prominent within the healthcare services for many years. It is proposed that a huge obstacle to successful implementation of POCT is a lack of a suitable interdepartmental management structure. It is suggested how the "silo" approach places too much emphasis on the management of individual departments, rather than giving consideration to the organisation as whole in a manner that emphasises the patient journey (Price, Kricka 2007). However, the implementation of a functional interdepartmental management structure is notoriously difficult (Zydron, Woodworth et al. 2011). Furthermore, it has been stated that poor understanding of managers, and also many clinicians, with respect to the clinical governance implications of key issues such as diagnostic performance, clinical and economic outcomes, organisational impact and cost-effectiveness of the patient episode makes it difficult to implement a whole-system approach to the implementation of POCT (Pearson 2006).

6. Reluctance to change health service practice.

It has been suggested within the literature reviewed that most organisations are subject to a "status-quo bias", which prevents change unless there is overwhelming evidence for significant improvements being gained in doing so (Zydron, Woodworth et al. 2011). In terms of POCT, this inherent bias against behavioural change within a healthcare service is seen as one of the largest managerial obstacles to its increased implementation. A number of articles cite a lack of evidence (or at least the occurrence of conflicting evidence) for the potential benefits and outcomes of implementing a POCT system, as making it hard to justify the necessary changes and economic outlay required (Zydron, Woodworth et al. 2011, Giuliano, Grant 2002, Freedman 2002).

The 2 most significant barriers in terms of staffing and operational issues are, firstly, reduced staff satisfaction levels and friction between clinical groups and, secondly, the effect of alternative diagnostic testing such as POCT on the existing clinical care pathways. It is suggested that clinical pathways must be adapted to accommodate the efficient use of POCT or else the

potential benefits available will not be obtained. Furthermore, it may transpire that the adapted pathways will somewhat allay concerns regarding increased workloads of front-line clinical staff.

The highest number of publications relating to management structure and clinical governance were found at the beginning of the review period (2000 to 2002), indicating that these issues have been of concern from the advent of POCT usage (in this century). The fact that in subsequent years the frequency of such papers tails off may be due to the increased acceptance of the central laboratory that acceptable diagnostic testing can now be achieved outside of their confines with adequate quality assurance protocols in place, and that furthermore that clinical care pathways are continuing to evolve to accommodate the use of safe and effective POCT.

15 of the 63 assessed articles were deemed as being primary or original research, with the remaining 48 being expert opinion or review pieces. The original pieces of research were assessed as a subset of the literature to determine any extra value could be accrued from the more robust methodologies applied. By way of assessment, of the 15 articles; 10 made reference to quality assurance & regulatory issues; 6 indicated economic issues; 5 noted device performance & data management issues, and; 2 cited staff & operational issues. An interesting finding here was that, of the 3 articles not citing any barriers to adoption, 2 of them were found to be original research. The indication here is that primary research studies, without the application of expert clinical opinion, may lack the capability to determine the impediments to POCT uptake. A consideration of the barrier categories themselves can explain the spread of citations here. The most cited category, quality assurance & regulatory issues, is one that can be defined through primary studies such as the investigation of testing error rates. While some assessment of economics can be made, such as a simple cost per test analysis, it is difficult to assess longer term economic impacts through primary research due to the difficulties in placing a financial value on improved quality of life due to the intervention of POCT in comparison to CLT. Likewise, original research studies can be used to assess some device performance, by comparing the results of different devices, however longer-term impacts become more difficult to gauge. Staffing & operational issues, cited by just 2 articles here, is very much a subjective area based on opinion, including the satisfaction levels of staff. As a result, it is difficult to use primary research to investigate this area. Less than 24% of the assessed literature here was found to be original or primary research, indicating the lack of primary research in the area and the difficulties in performing such. As a result of this, and due to the subjective nature of some of the research area, all research articles assessed have been treated as equal without a "hierarchy of evidence" applied in this case. However, the importance of robust and original research is recognised and it is the intention of this body of research to produce such.

A summary of the various barriers identified in this study, along with the corresponding references, is provided in Table 3.3.

Table 3.3 – Summary of impediments identified.

Category	Specific Impediment	References
Economic issues:	The cost per test of POCT is higher than traditional central laboratory testing.	(St-Louis 2000, Vashist, Luppa et al. 2015, Price 2001, Huckle 2006, Price 2002, Huckle 2008, Crook 2000, Creed 2001, FitzGibbon, Huckle et al. 2010, Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Goodwin 2008, Cvitkovic 2011, Lee, Shin et al. 2011)
	The cost-effectiveness of a POCT system is difficult to gauge and cost comparison studies against traditional central laboratory testing methods are complex.	(Fermann, Suyama 2002, Goodwin 2008, Lewandrowski, Flood et al. 2008, Lee-Lewandrowski, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Lee-Lewandrowski, Lewandrowski 2001, Hortin 2005, Zydron, Woodworth et al. 2011, St-Louis 2000, Rajendran, Rayman 2014, Foster, Despotis et al. 2001, Giuliano, Grant 2002, Louie, Tang et al. 2000, Crook 2000, Nichols 2005)
	The initial costs of implementing a POCT system can be high.	(Lee-Lewandrowski, Lewandrowski 2009, Zydron, Woodworth et al. 2011, Foster, Despotis et al. 2001, Vashist, Luppa et al. 2015, Nichols 2003, Boonlert, Lolekha et al. 2003, Blick 2001, FitzGibbon, Huckle et al. 2010)
	The allocation of budgets for POCT is not appropriate.	(Huckle 2006, Huckle 2008, Creed 2001, FitzGibbon, Huckle et al. 2011)
	Reimbursement is a major hurdle to POCT implementation.	(FitzGibbon, Huckle et al. 2011, FitzGibbon, Huckle et al. 2010, Gregory, Lewandrowski 2009,

		Blick 2001, Vashist, Luppa et al. 2015, Huckle 2006, Melo, Clark et al. 2011, Huckle 2010)
	Reference to economic issues in a non-specific manner.	(Pearson 2006, Migliore, Ratti et al. 2009, McNerney, Daley 2011, FitzGibbon, Brown et al. 2007, Halpern 2000, Linder 2007, Dhawan, Heetderks et al. 2015, Freedman 2002)
Quality assurance & regulatory issues:	Device operation by untrained or non-competent staff.	(Vashist, Luppa et al. 2015, Pearson 2006, O'Kane, McManus et al. 2011, Nichols 2003, Rajendran, Rayman 2014, Kiechle, Main 2000, Meier, Jones 2005, Crook 2000, Creed 2001, Luppa, Müller et al. 2011, Louie, Tang et al. 2000, Briggs, Kimber et al. 2012, Halpern 2000, Fermann, Suyama 2002, Lee-Lewandrowski, Lewandrowski 2009, Giuliano, Grant 2002, Huckle 2006, Nichols 2005, FitzGibbon, Meenan et al. 2007, FitzGibbon, Huckle et al. 2010)
	Complex regulatory requirements.	(Cvitkovic 2011, Plerhoples, Zwemer et al. 2004, Creed 2001, Linder 2007, Groves 2005, Gregory, Lewandrowski 2009, Lee-Lewandrowski, Corboy et al. 2003, Lee-Lewandrowski, Lewandrowski 2001, Lewandrowski, Flood et al. 2008)
	Product qualification.	(Tantra, van Heeren 2013, Huckle 2008, McNerney, Daley 2011)
	Reference to quality assurance & regulatory issues in a non-specific manner.	(St-Louis 2000, Murray, Fitzmaurice et al. 2004, Price, Kricka 2007, Melo, Clark et al. 2011, Huckle 2010, FitzGibbon, Huckle et al. 2010b, FitzGibbon, Huckle et al. 2010a, FitzGibbon, Brown et al. 2007, Boonlert, Lolekha et al. 2003, FitzGibbon,

		Huckle et al. 2011, Lee, Shin et al. 2011)
Device performance & data management issues:	Reduced analytical performance in comparison to centralised laboratory testing.	(Zydron, Woodworth et al. 2011, You, Chung et al. 2013, St-Louis 2000, Vashist, Luppa et al. 2015, Shephard 2011, Sheikholeslam, Pritzker et al. 2011, Perry, Fitzmaurice et al. 2010, Knaebel, Irvin et al. 2013, Nichols 2005, Rebel, Rice et al. 2012, Rajendran, Rayman 2014, Murray, Fitzmaurice et al. 2004, Melo, Clark et al. 2011, Huckle 2008, Huckle 2010, Carraro, Plebani 2009, Louie, Tang et al. 2000, FitzGibbon, Brown et al. 2007, Goodwin 2008)
	Connectivity and data management problems.	(Swayze, Rich 2012, St-Louis 2000, Vashist, Luppa et al. 2015, Rajendran, Rayman 2014, Kiechle, Main 2000, Meier, Jones 2005, Huckle 2010, Carraro, Plebani 2009, FitzGibbon, Huckle et al. 2010, Halpern 2000, Gregory, Lewandrowski 2009, Blick 2001, Goodwin 2008, Lee-Lewandrowski, Lewandrowski 2001, Cvitkovic 2011, Nichols 2003, Crook 2000, Groves 2005, Fermann, Suyama 2002)
	Poor usability of devices.	(Swayze, Rich 2012, Crook 2000, Goodwin 2008, Linder 2007, Nichols 2005, Dewsnap, Mcowan 2006)
Staff & operational issues:	Reduced levels of staff satisfaction and increased friction between staff groups.	(Zydron, Woodworth et al. 2011, Fermann, Suyama 2002, Giuliano, Grant 2002, FitzGibbon, Brown et al. 2007, Halpern 2000, FitzGibbon, Meenan et al. 2007, Blick 2001, Huckle 2010)
	Resistance of the central laboratory to pass control of testing to others.	(Fermann, Suyama 2002, Huckle 2008, Halpern 2000, Huckle 2010)

	Inappropriate use of POCT.	(Crook 2000)
	Alterations to diagnostic testing for clinical care pathways.	Zydron, Woodworth et al. 2011, Price, Kricka 2007, Huckle 2008, Huckle 2010, FitzGibbon, Huckle et al. 2011, Lee-Lewandrowski, Lewandrowski 2001, Price, Kricka 2007, Price 2001, Price 2002)
	No existing interdepartmental management structure with clear clinical governance for POCT.	(Zydron, Woodworth et al. 2011, Pearson 2006, Price, Kricka 2007)
	Reluctance to change health service practice.	(Zydron, Woodworth et al. 2011, Giuliano, Grant 2002, Freedman 2002)

This in-depth systematic literature review has identified a number of impediments to the more widespread adoption of POCT within the clinical environment. The issues concerned have been categorised and their significance assessed in terms of the prevalence of each within the set of papers identified. The most significant barriers, real or perceived, can be seen as being interlinked in a number of ways. If the actual cost-effectiveness of a POCT system could be more accurately determined, including the inclusion of the longer-term benefits, then the higher cost per test of POCT when compared on a like-by-like basis with traditional CLT could be more readily justified. Furthermore, a number of the impediments to adoption of POCT devices emanate from their more dispersed nature of in the healthcare setting, including appropriate data management and maintaining compliance with regulatory requirements. It is possible that improving the connectivity of such devices with patient record systems could support the development of adequate solutions to these and related barriers to adoption. If clinical pathways can be effectively adapted to work with the dispersed nature of POCT systems, then more of the potential benefits can be realised without any fear of reducing the quality of the analytical information. In this way, staff satisfaction and confidence in the systems would be improved. Clearly, further work is required to demonstrate the health and economic benefits of adopting POCT in specific clinical pathways.

With respect to satisfying and achieving the objectives of this body of research, the study described here has attended to the first 3 objectives as defined in Chapter 1, namely; to determine from a systematic review of the academic literature the actual issues that affect the adoption of POCT devices within the hospital-based clinical environment; to categorise the issues identified from the literature as a means of understanding in detail their relative contribution to adoption of POCT devices in the hospital environment, and; to determine, in order of priority, which issues are currently impacting the adoption of POCT devices within the

clinical environment. Firstly, the barriers to adoption have been identified from the relevant academic literature base. Secondly, these barriers have been categorised accordingly into the 4 classifications as has been described in this chapter. Thirdly, the identified barriers have been assessed with respect to their frequency of citation amongst the evaluated literature, with the categories defined in an order of priority. The basis of this order is determined by taking frequency of citation within relevant literature as a measure of impact upon POCT uptake throughout the assessed time-period.

The categorisation approach adopted here is seen as a significant step in overcoming the identified barriers to adoption and facilitating the more widespread use of POCT devices within the clinical environment. It is recognised that some of the findings from the literature that have been assessed in this study are somewhat anecdotal and so direct further primary research of clinical opinion has been undertaken to separate real from perceived. In this way, it is intended that the most significant impediments to the adoption of POCT will be identified and solutions to overcome them devised as per the overall aims and objectives of this thesis.

Chapter 4

Clinical Perspectives on Barriers to Adoption of POCT from within the UK National Health Service (NHS)

4.1 Study Objective

The substantial systematic review of published literature reported in Chapter 3 has identified and categorised the various issues that are deemed to act as impediments to the more widespread uptake of Point-of-Care Testing (POCT) within the clinical environment. However, much of the information presented in these publications has been found to be anecdotal and at times the information provided appears to be contradictory. Hence, the purpose of the study reported here is to gain primary data that can be used to verify the key issues that determine at first hand clinical perspectives on the utility of POCT within the UK National Health Service (NHS). Clearly, attaining direct clinical experience and relevant opinion on the real and/or perceived issues affecting POCT uptake is crucial in order to provide solutions that can maximise their future function and utility. The aim of the study is therefore to capture the opinion of clinicians in regard to their experience of POCT usage and to collate the various advantages and disadvantages that this form of testing offers to medical diagnostics in the hospital healthcare sector. The fundamental considerations are threefold: (1) to assess the significance of the categories of barrier to adoption of POCT identified from the systematic review of the published literature; (2) to assess the relevance of these considerations within the hospital-based clinical environment, and (3) to prioritise each category in terms of its current impact on the effectiveness of clinical diagnostics. Hence the outcomes from this study will be used to supplement and augment the information derived from the published works reviewed with regard to identifying any further issues that might contribute to the clinical uptake of POCT devices. In this respect, the key research objective addressed here can be stated as determining, in order of priority, the issues that are currently impacting the adoption of POCT devices within the hospital-based clinical environment.

As a key theme of this research is to provide a solutions-based approach, the study also aims to gain valuable clinical opinion on how to overcome the core issues i.e. what are the most effective routes to increased uptake of effective POCT within the clinical environment?

4.2 Study Development & Design

A survey tool was identified as being the most appropriate and effective method to collect the required primary source information and subsequently a draft questionnaire was developed, with the issues identified from literature at the core of the questions used therein. Initial consultations with senior cardiologists (n=4) provided a means to carry out a pilot study of the survey tool. These initial engagements were carried out in a face-to-face interview format and the outcomes indicated that the survey should be amended to include the following features:

- Tick boxes to allow the more rapid completion of the survey; and
- A visual scaling system, using a 1 - 10-point scale similar to that already used by senior clinicians in the appraisal of junior doctors should be adopted for questions requiring a semi-quantitative response.

The amended study tool underwent a second pilot phase via face-to-face interviews with a sample (n=2) of senior hospital based acute care clinicians and based on the additional feedback received, some further refinement of the structure and language was undertaken. The survey study questionnaire was then passed through a third and final pilot phase consultation process with the assistance of clinical bioscience professionals (n=2). This third pilot phase was conducted via 2 different survey formats; a face-to-face interview and also via an electronic submission. The latter aspect was facilitated to gauge the effectiveness of the remote completion of the final form of the survey tool. Following the various stages of pilot scale clinical validation, the survey tool, data acquisition process and analysis methods were critiqued in order to ensure that the questionnaire would attain sufficient data to be able to address the key research aims of the study.

The final survey design comprises 26 core questions and focuses on the most prevalent impediments to adoption of POCT found within the relevant literature, categorised into 4 key areas: (1) economic issues; (2) quality assurance and regulatory issues; (3) device performance and data management issues and (4) staff and operational issues. The operational version of the questionnaire utilised in this study can be found in Appendix A.

The survey study utilised 2 avenues to attain the primary information required to meet the core objectives. Firstly, in-depth face-to-face interviews were carried out to acquire detailed opinions on the potential advantages, disadvantages and overall clinical utility of POCT from senior (consultant-level) clinicians. Secondly, an online electronic version of the survey aimed at a range of clinician specialisms was used to maximise participation and hence increase the overall value of the information collected. Both configurations of the survey tool included an identical question set in order to ensure results would be directly comparable.

In terms of study execution, due to the geographical location of the project base, the 5 Health & Social Care Trusts in Northern Ireland (HSCNI) were selected as a representative sample of the UK NHS. Subsequently, an adjunct study was carried out at a Healthcare Trust in England (Frimley Health Foundation Trust) as a means to verify that the findings from the NI Healthcare Trusts were a true representation of the wider UK NHS system.

The study was peer reviewed and duly authorised by the Faculty of Computing and Engineering Ethics Filter Committee, in accordance with Ulster University's research governance guidelines. Subsequently, the study was further assessed via the NI Research & Development Application Gateway (http://www.research.hscni.net/ni-rd-application-gateway) in order to attain the required research governance approvals from all of the participating Health Trusts. The HSCNI Southern Trust acted as the Lead Trust in terms of the research governance approval process. The approval process was then extended to Frimley Health Foundation Trust via the Gateway process. In the latter case, the requirements were slightly different than that for the HSCNI system and difficulties were encountered in translating the individual Trust placement agreements to the "research passport" system used in the wider NHS system that operates in England and Wales. As a result of this added complexity and the associated time pressures, the Frimley aspect of the study was reduced to electronic participation only, which allowed the local research & development department at this Trust to process the approval directly through a time efficient process.

The Chair of the POCT Committee in each participating NI Health Trust agreed to act as a local collaborator for the study and aided in the identification and recruitment of consultant-level clinicians with a knowledge of the clinical utility of POCT to participate in the face-to-face interviews. Furthermore, the local collaborators directly assisted with the distribution of the electronic survey amongst appropriate specialist-level colleagues with a knowledge of the clinical utility offered by POCT diagnostics.

4.3 Study Results

In consideration of the primary study conducted within the 5 NI Health Trusts, 27 face-to-face interviews with consultant level clinicians were carried out and a further 21 specialised clinicians participated through the electronic form of the study, giving a combined total of 48 responders.

It was decided that an appropriately managed assessment of the 2 streams of survey responses collected by the study, i.e. from the face-to-face and electronic versions was necessary to ensure that they could be a considered as a uniform data set and the answers grouped accordingly. Hence, a process of analysis was devised in order to determine if these data could be amalgamated with sufficient integrity. The free-response questions included in the question set

were not subjected to the grouping test process due to the likelihood of high variability in the answers obtained. Analysis was carried out via a comparison of the response distribution across the scaled answers from both streams of the survey data, with all but 2 questions being deemed appropriately comparable. The 2 questions flagged as not being sufficiently comparable in terms of response distribution are addressed later.

Table 4.1 provides a breakdown of study participants in terms of their clinical specialty. Emergency medicine clinicians are clearly the most represented within this study, with 15 participants.

Table 4.1 - Breakdown of study participants with respect to clinical speciality (n = 48).

Clinical Specialty	**Number of Respondents**
Emergency Medicine	15
Clinical Biosciences	7
General Medicine	7
Anaesthetics & Intensive Care	6
Paediatrics	3
Obstetrics & Gynaecology	3
Cardiology	2
Respiratory	2
Renal	1
POCT Experts[1]	2

All 48 respondents indicated that POCT devices were used to diagnose patients in their area of clinical practice. Participants were asked to give an estimation of how many tests were performed using POCT as a percentage of all diagnostic tests performed in their area of clinical practice, with an average figure of 20% returned based on 44 responses (4 participants were unable/unwilling to provide a value).

Figure 4.1 indicates a measure of proficiency and training in the practical use of POCT devices declared by respondents. It should be noted that it was not a necessary requirement for participants to have personally used the devices, but rather the focus was more on knowledge of the clinical utility that this particular type of diagnostic testing device can offer. The majority of study participants ranked themselves as having a basic level capability (unsupervised use) (21

[1] Trust Lead Pharmacist and Anti-Coagulation Specialist Nurse were identified as having expert knowledge on the area and were subsequently invited to participate.

of 48 respondents), or as being competent (unsupervised use and maintenance of devices) (17 of the 48 respondents).

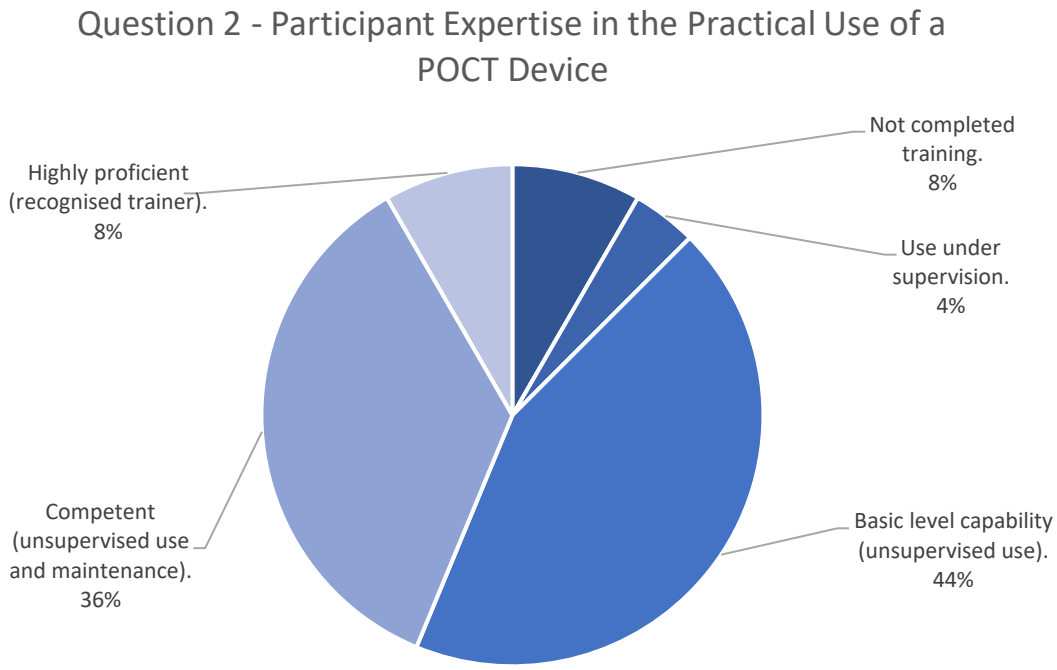

Figure 4.1 - Levels of expertise in the personal use of POCT devices of study participants (n=48).

Figure 4.2 outlines the most common types of point-of-care test used in the respective clinical care area of study participants. Blood gas and blood glucose tests were the most dominant being indicated by 85% and 79% of respondents respectively. This is perhaps unsurprising due to their embedded use within healthcare pathways in the UK. Two other tests specified by over half of the clinicians within the study were urine pregnancy tests (54% of respondents) and blood lactate tests (52% of respondents). Although not prevalent amongst the main list of tests reported, the following were additionally utilised by a notable portion of respondents, albeit with their use being less prevalent; C-reactive protein (CRP), rupture of membranes (ROM), bilirubin, neutrophil gelatinase-associated lipocalin (NGAL), faecal occult, foetal scalp pH and other blood chemistries including D-dimer and platelet function testing.

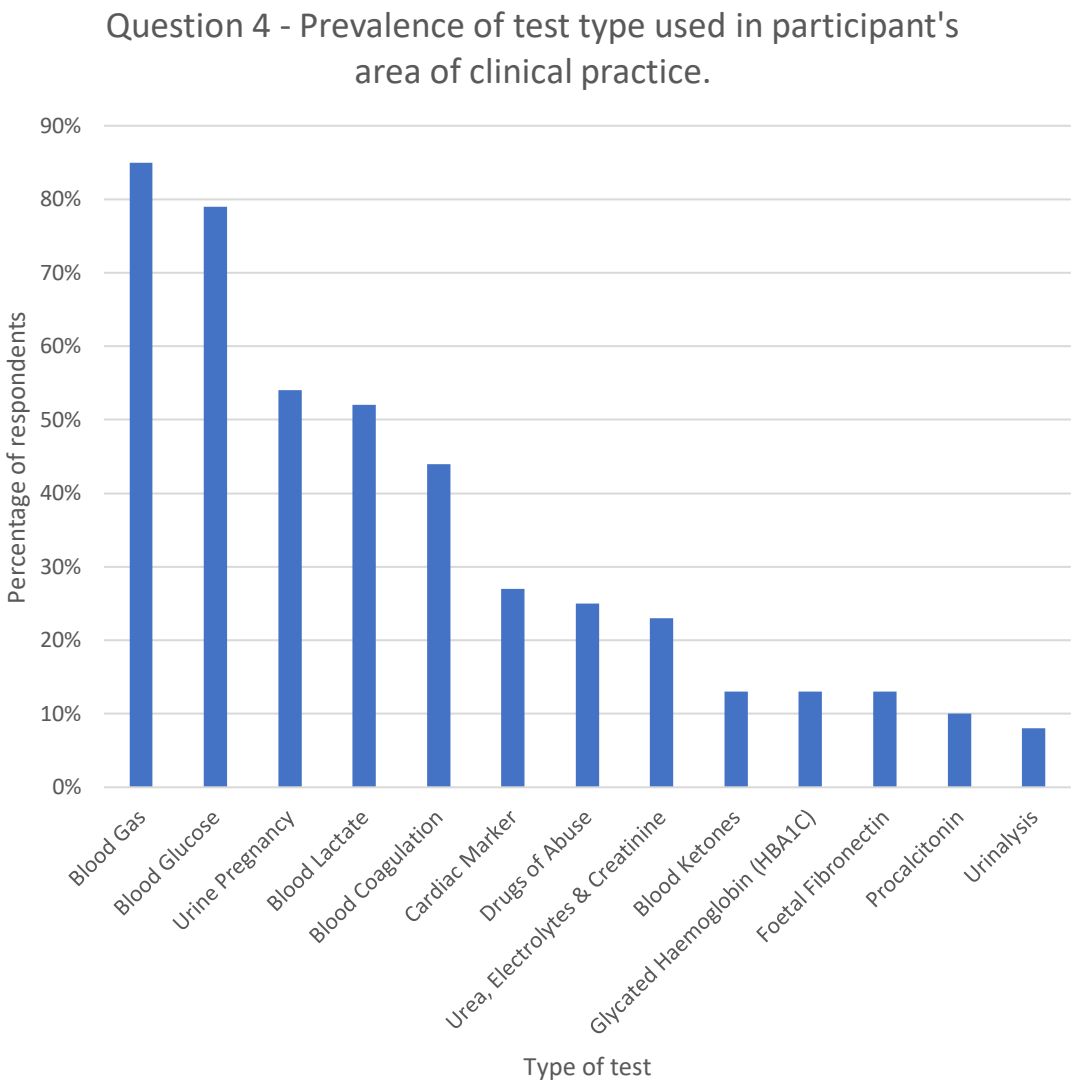

Figure 4.2 - Most common POCT devices used in participant's area of clinical practice with respect to percentage of respondents (n=48).

In this primary survey study, the vast majority of respondents (94%) indicated that they had never experienced any level of patient mistrust of POCT devices. Only 3 of the 48 study participants claimed to have experience of patients querying the capability of a POCT device, with 1 clinician interviewed stating that this was exclusively *"on the occasion that POCT blood glucose results were not normal and the patient knew that their levels were well controlled"*. The same clinician was of the opinion that this was in fact not a negative aspect of the process of near-patient testing and that such patient queries could be used to re-check devices to ensure that they were calibrated correctly and that the result was indeed correct. Notwithstanding this report, none of the participants indicated any experience of patients requesting evidence of the capability of a POCT device or refusing to have a test carried out using a POCT device.

4.3.1 Economic Issues

Clinicians were questioned about a number of issues pertaining to economic considerations associated with POCT operation that were attained from the systematic review of the published literature. In terms of the actual cost per test of POCT, 36 out of 48 respondents (75%) agreed that it was higher than that of a comparable analysis sourced through central laboratory testing (CLT), as indicated in Figure 4.3. In comparison, just 15% of respondents disagreed with this statement, while 10% were either not sure or did not provide a response.

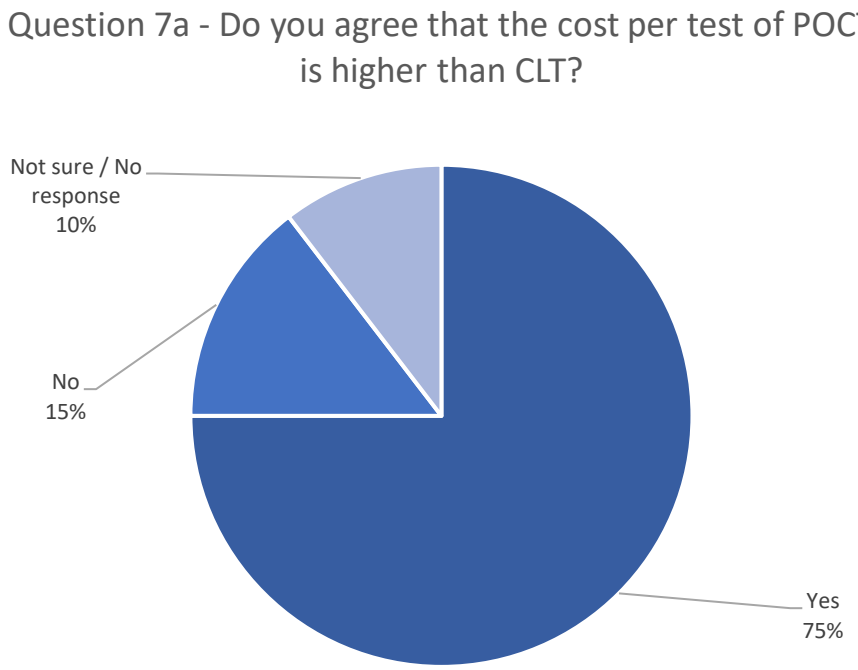

Figure 4.3 - Clinician indication of POCT cost per test in comparison to CLT (n=48).

Notable comments obtained from those in agreement with the higher cost of POCT included:

- *"The dilemma is increased cost versus quicker turnaround times."*
- *"Yes, but this doesn't take into account the cost of staff in the lab."*

Clinicians were also asked to rate their agreement or otherwise with the statement that POCT provides longer term economic benefits, for example reduced hospital stay, reduced outpatient appointments, etc. These responses were given on a 10-point scale, with the distribution of opinion outlined in Figure 4.4. Whilst a significant proportion (38%) of responses were neutral, over half of responses (52%) either "agreed" or "strongly agreed" with the question posed here. Just 10% of participants "disagreed" or "strongly disagreed" with this statement.

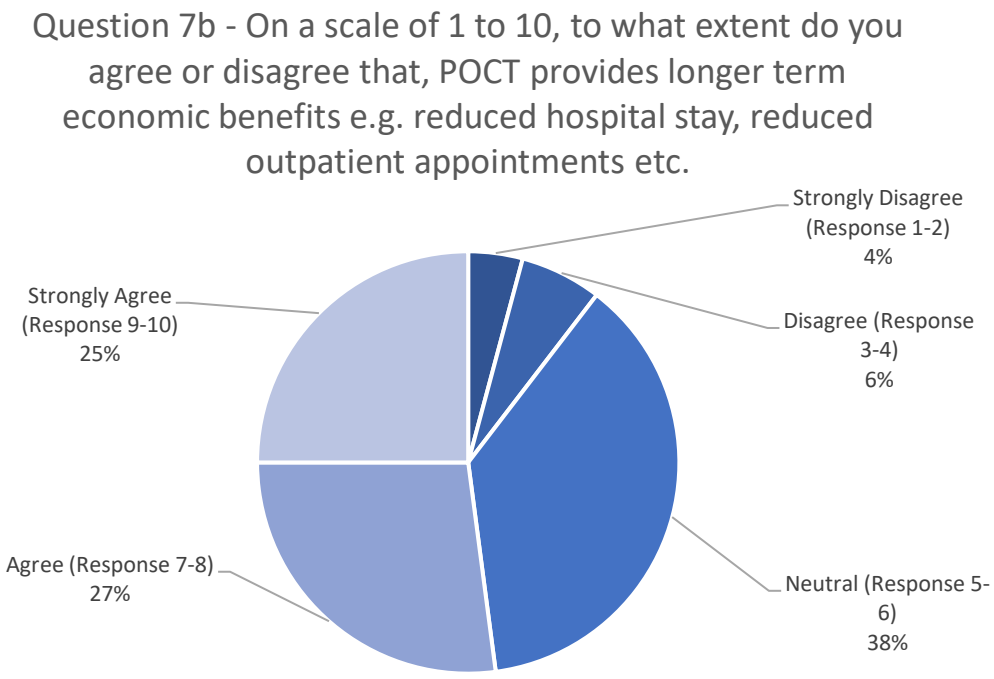

Figure 4.4 - Clinician opinion on the longer term economic benefits attainable through the use of POCT (n=48).

One consultant who "agreed" with the statement added that *"POCT reduces time spent by patients in the Emergency Department (ED). Audits show that the central laboratory can't meet the required one-hour vein-to-brain time as they claim."*

The 5 respondents whose opinions were within the 1-4 are of the scale were asked why the longer term economic benefits theoretically available through the use of POCT were not being realised fully within their institution. Their responses were as follows.

- *"With a good laboratory infrastructure already in place here, POCT merely duplicates an existing service."*
- *"It is difficult to quantify and prove these savings down the line, POCT does not radically alter patient management or treatment."*
- *"There is not a high enough volume of tests performed using POCT."*
- *"I don't think there are longer term economic benefits, there are only clinical benefits to bedside diagnosis."*
- *"My main experience is prior to admission, I couldn't say if POCT is being used to expedite discharge decisions."*

Despite the perceived higher cost per test of POCT, as indicated in Question 7a (Fig. 4.3), clinicians also tended to be of the opinion that the use of a POCT system is in fact cost-effective, with 36 out of the 48 participants (75%) indicating that this was the case, as displayed in Figure

4.5. By comparison, 17% of participants did not believe that the use of such a near patient system is cost-effective, with 8% not sure or unable to give a response. Comments obtained from these consultants included the following:

- *"Quick decisions outweigh the extra costs."*
- *"On paper, yes, but you need clear clinical pathways and adherence to these pathways. Costs versus quality of care is the dilemma."*

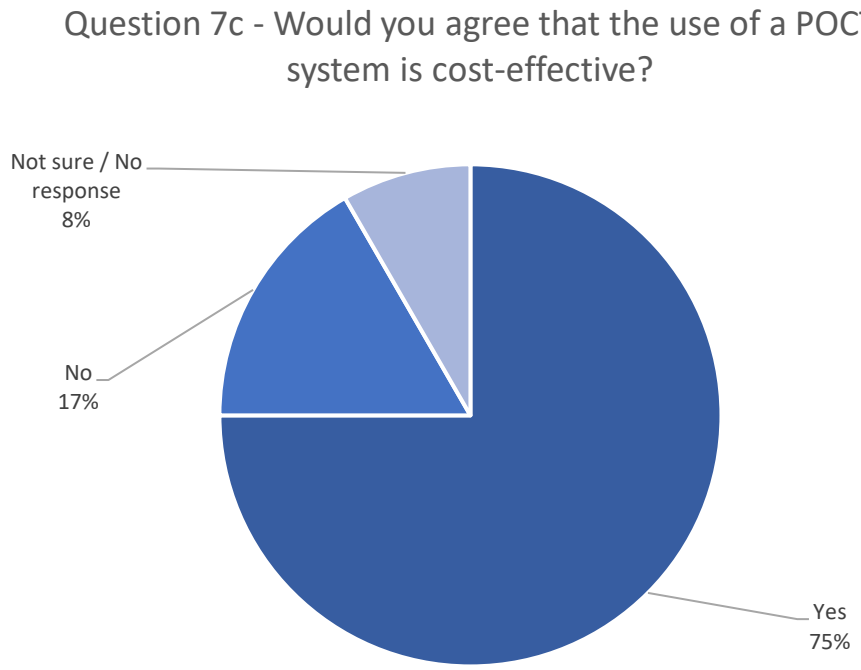

Figure 4.5 - Clinician indication of the cost-effectiveness of a POCT system (n=48).

Study participants were questioned about procurement, reimbursement and budgeting for POCT with respect to the interdepartmental nature of such testing. Sharing of POCT resources between departments was identified in the literature as being problematic in terms of determining who actually pays for both the devices and test strips/cartridges. As shown by Figure 4.6, responses on this topic were found to be very varied with the clinical opinion obtained showing no particular trend.

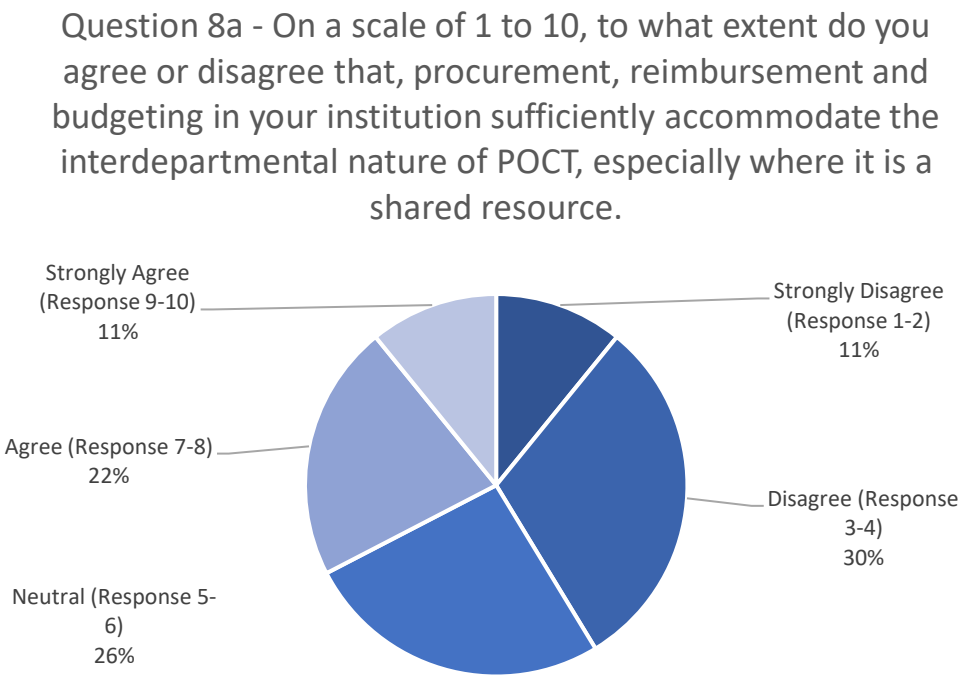

Figure 4.6 - Clinician opinion on procurement, reimbursement and budgeting for POCT with respect to the interdepartmental nature of such devices (n=46).

One consultant who "agreed" with this statement added that there was no interdepartmental sharing of devices in their institution, while another commented that interdepartmental use was beginning to be prohibited in order to eliminate risk of cross-infection issues. Hence, it is possible that this type of reduction in sharing of devices between departments within clinical institutions may be partly responsible for the varied response to this particular question. Of the 19 respondents who "disagreed" or "strongly disagreed" with the statement in this question, 17 indicated that it did in fact make it difficult to employ the POCT devices effectively. Some comments added by these individuals include:

- *"Our POCT Blood Gas Analyser is abused by the ward regularly, but we also use drugs testing from the Emergency Department."*
- *"A lot of people don't understand the benefit of POCT, the ward is picking up the cost for using POCT rather than the lab, even though it is taking work off the lab and the ward is not being funded for it."*
- *"All the money comes out of one pot. This would be easier to manage if there was a centralised budget for POCT."*

Study participants were subsequently questioned on the relevance of a range of economic issues within their own clinical institutions including; difficulties in justifying the use of POCT due to the higher cost per test in comparison to traditional testing methods; difficulties in justifying the

implementation of a POCT system due to unclear cost-effectiveness and complexities in making accurate comparisons to traditional methods of testing; difficulties in justifying the implementation of a POCT system due to high initial outlay costs; issues with regards to budget contributions due to the "silo" nature of separate departmental budgeting, and; difficulties in obtaining reimbursement for POCT. The distribution of responses to these questions are outlined in Figure 4.7. For the most part, opinion appears to be significantly varied. It was apparent from respondent comments that much of this variation with regards to the economic issues was based on the dilemma of increased costs versus improved quality of care. Whereas, some institutions seemed to act solely on clinical justification, others tended to be of the opinion that the benefits of POCT were much exaggerated and that in reality such devices do not provide the clinical benefits promised. In this respect, the increased cost is seen as a very relevant and significant impediment to their adoption. The strongest trend shown here was to indicate that any difficulty in obtaining reimbursement for POCT is not a relevant issue within the UK clinical institutions, with 20 of 45 respondents (44%) specifying this response. Comments added by consultants who were of this opinion included *"reimbursement will come out of the lab budget"* and *"the only problem is getting the upfront money to get the device in the first place"*. It should be noted that part (b) of this question was one of the 2 questions that were flagged for having a notable amount of variation between responses from the face-to-face and electronic versions of the survey tool. Whereas, the electronic responses had strong variation across all categories, the face-to-face participants were quite polarised in their opinion, with 20 of 27 responses being in the "not relevant" or "very relevant" categories. Perhaps, an explanation for this may lie in the seniority of respondents. All face-to-face participants were at consultant level, while electronic participants represented a range of specialisms, from trainees upwards. It is therefore possible that a more polarised opinion is found within the face-to-face responses here is due to the stronger opinions held by consultant-level clinicians that has been gained through a greater wealth of experience of POCT implementation. By comparison, many of the respondents in the electronic survey may not yet have developed a strong opinion one way or the other.

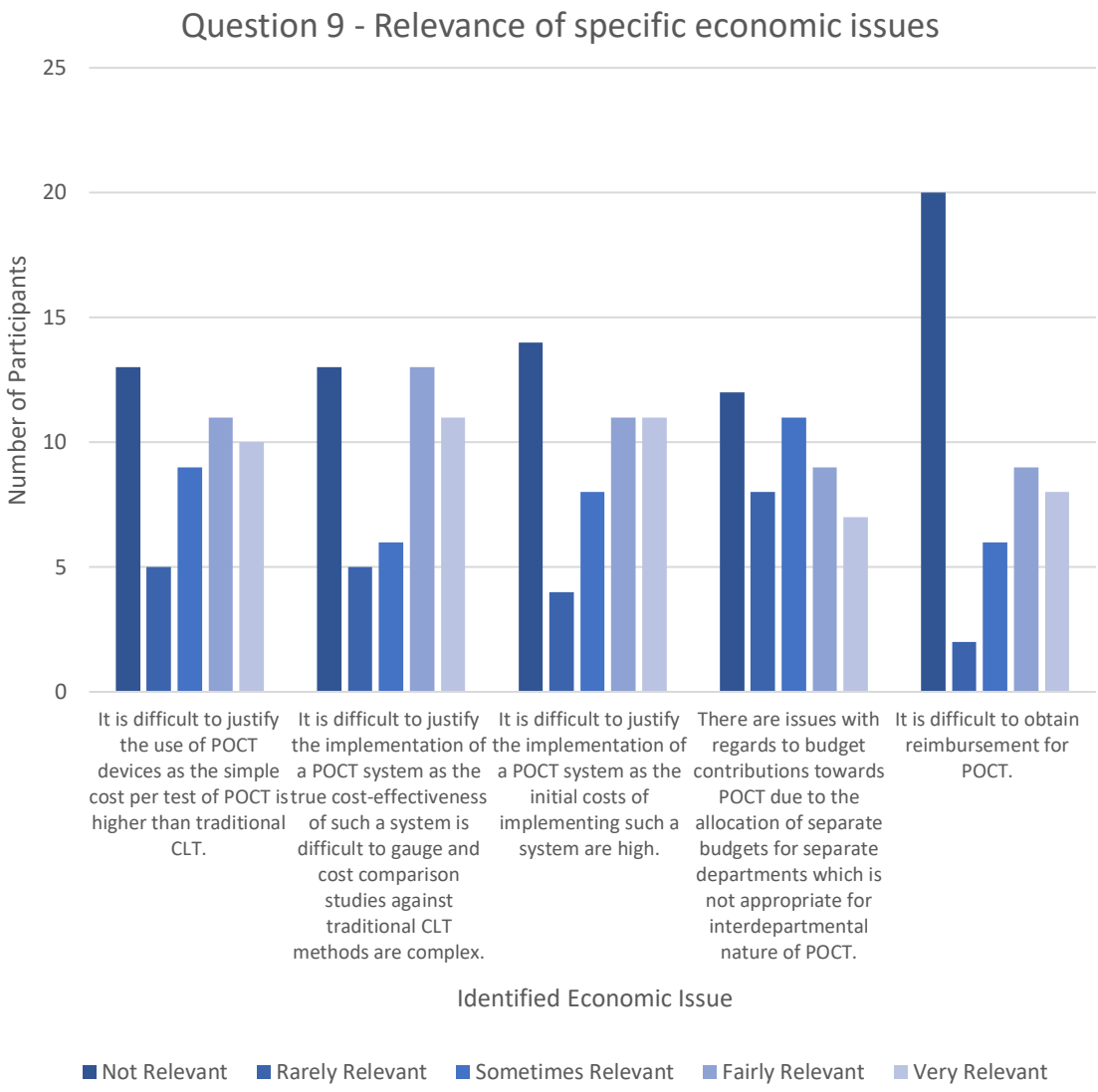

Figure 4.7 - Clinician opinion on relevance of specific economic issues within their own clinical institution (n=48).

4.3.2 Quality Assurance & Regulatory Issues

With regards to concerns involving quality assurance and regulatory procedures, clinicians were questioned on the most commonly noted of these issues that arose from the systematic review of the academic literature. The initial focus was on how the dispersion of POCT devices across the clinical environment contributes to their (potential) use by untrained or non-competent staff. Participant responses to this question are outlined in Figure 4.8. The most dominant response to this particular question were in the "agree" and "strongly agree" categories of the 10-point scale, with 29% of participants responding in each. By comparison, the "disagree" and "strongly disagree" categories were specified by 15% and 10% of respondents. respectively, whilst 17% of clinicians gave a "neutral" response.

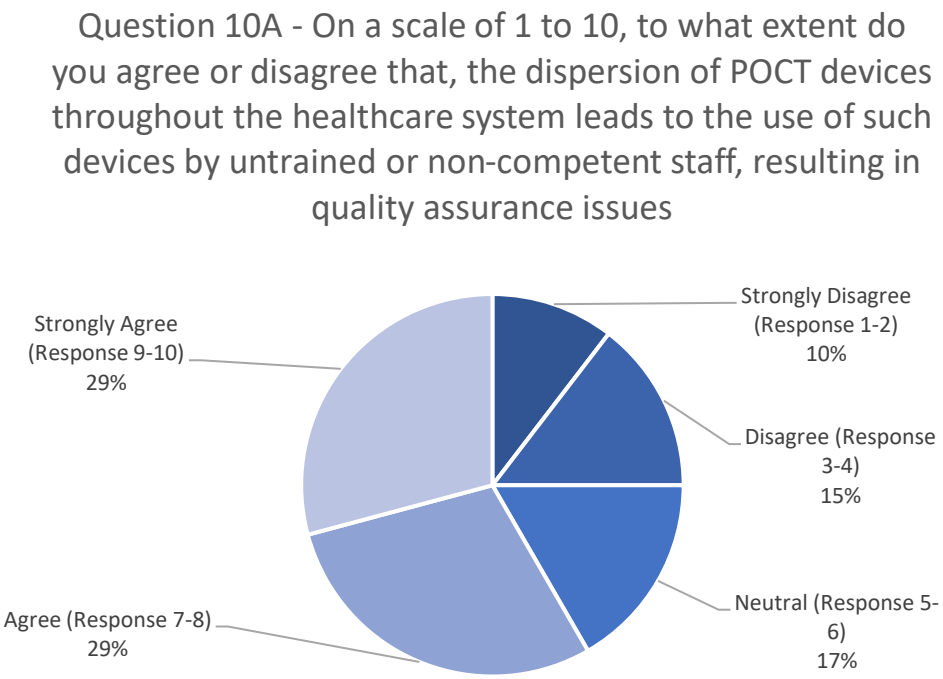

Figure 4.8 - Clinician opinion on how the dispersed nature of POCT devices leads to use by untrained or non-competent staff, resulting in quality assurance issues (n=48).

Comments by consultants interviewed face-to-face who disagreed or strongly disagreed with this statement indicated that the majority were of the opinion that *"tight enough"* controls were in place in order to overcome such a risk. In particular, the use of operator specific barcodes to access the devices and the maintenance of detailed training records, were cited as examples of good practice in this regard. However, overall 28 of the total 48 respondents "agreed" or "strongly agreed" that this aspect of POCT practice led to problems in trusting the test data generated. Furthermore, 18 of these 28 particular individuals indicated that these specific issues made it more difficult to utilise POCT to attain a timely and reliable diagnosis in comparison to that offered by CLT.

Participants were questioned on the complexity of current regulations for analytical testing accreditation for POCT. It should be noted that from the face-to-face interviews it was apparent that a number of clinicians were entirely unaware of the regulatory requirements, resulting in 6 participants within this cohort choosing not to answer this question due to a lack of knowledge. Responses to this question are outlined in Figure 4.9. The most dominant response here was that of a "neutral" standing, with 15 of 42 participants (36%) giving this opinion. The apparent lack of knowledge noted may have contributed to this neutral response. Response to this question was generally varied. One consultant participating within the face-to-face aspect of the study and who was in agreement with this statement added that there was "*therefore an increased risk of mistakes by operators*" due to this complexity. However, another consultant

interviewed who disagreed with this statement commented "*they are not overly complex, the problem is that regulations aren't available for all types of POCT device as there is a lack of standardisation*".

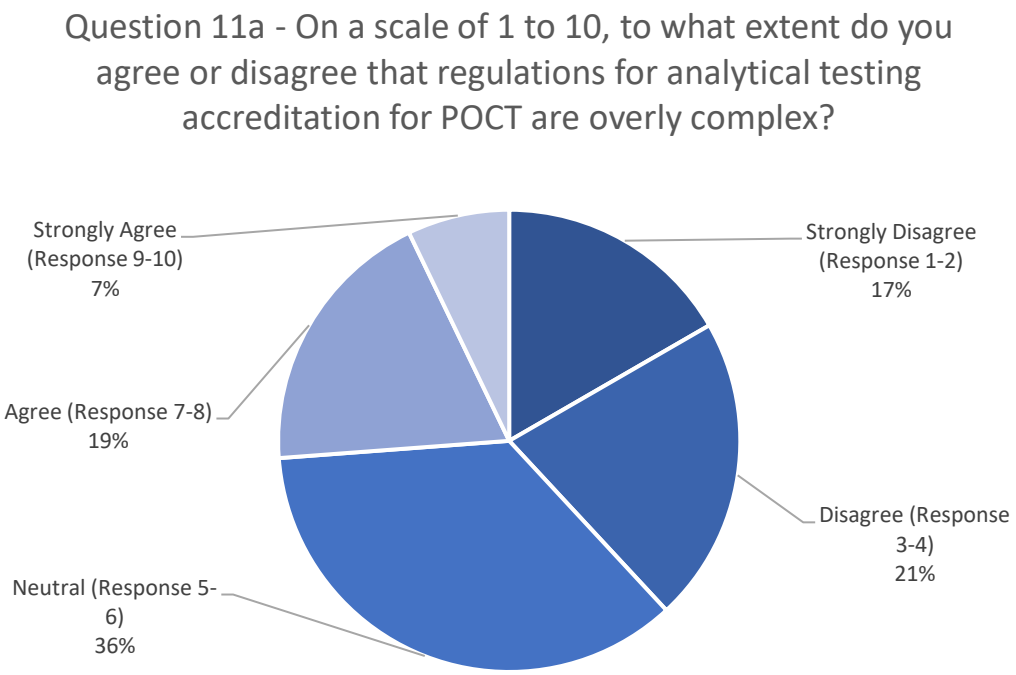

Figure 4.9 - Clinician opinion on the complexity of regulatory requirements for analytical testing accreditation of POCT (n=42).

Of the 11 respondents who returned in the 7-10 range of the ranking scale for this question, 8 subsequently believed that this complexity made it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT. The 3 in disagreement here believed that the over-complexity of POCT impacted negatively upon quality management, rather than on the day-to-day usage of such devices.

In consideration of compliance with regulations that apply to the operation of POCT devices, clinicians were asked for their opinions on the level of operator training and support provided to them by their central laboratory service. The results are outlined in Figure 4.10. Almost half of the 48 participants (48%) indicated that the level of training and support provided was either "high" or "very high". However, it should be noted that a significant number of respondents who returned answers in the "neutral", "low" and "very low" categories indicated that was due to the fact that manufacturers provided operator training and support rather than the central lab, an arrangement that they indicated that they were happy with. Of the 12 respondents in the "low" category, 9 indicated that this lack of training and support did not make it more difficult to attain a timely and reliable diagnosis in comparison to the case when utilising CLT.

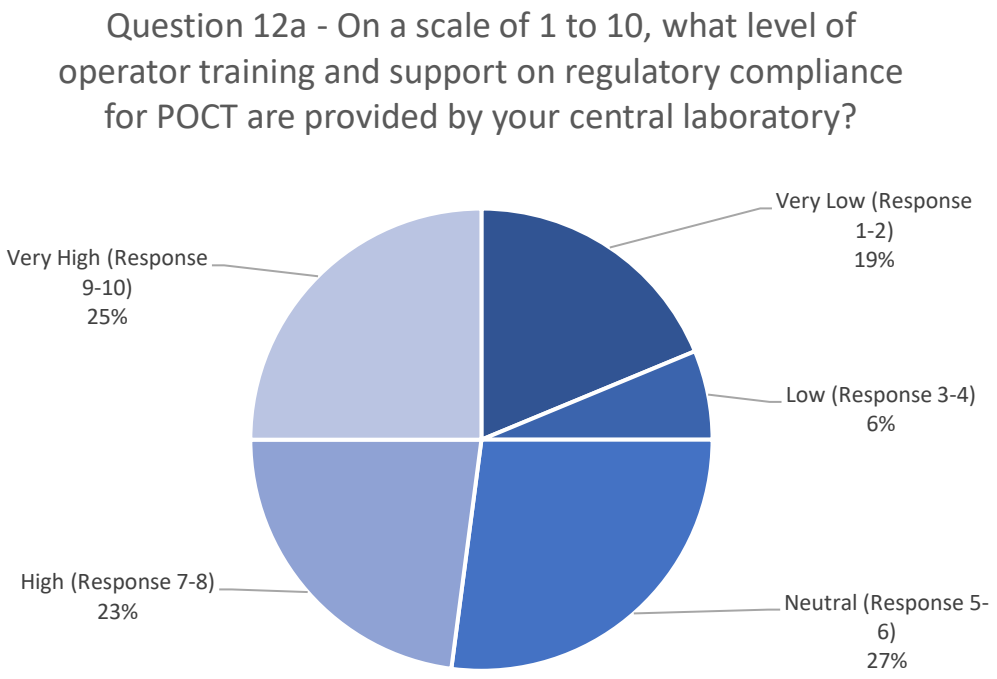

Figure 4.10 - Clinician opinion on the level of operator training and support on regulatory compliance for POCT provided by their central laboratory (n=48).

With regard to the relevance of quality assurance and regulatory issues within the local clinical institutes of study participants, Figure 4.11 outlines respondent opinion on specific issues found to be prevalent within the reviewed literature, namely; errors caused by incorrect quality assurance procedures; untrained/non-competent staff operating the devices; issues for non-laboratory operators of devices due to regulations written for traditional laboratory equipment being blindly applied to POCT; issues with maintaining regulatory compliance due to a number of changes in the regulations; issues with maintaining regulatory compliance due to the dispersed nature of POCT, and; a lack of development of POCT devices caused by product approval hurdles that discouraging economic investment in their development. It should be noted that a number of face-to-face participants chose not to answer any of the 3 questions regarding accreditation regulations (13b, 13c and 13d) due to a lack of knowledge on the area (4, 7 and 6 participants, respectively) and that 4 clinicians did not answer the question regarding product approval hurdles (13e), again due to a lack of knowledge in the area.

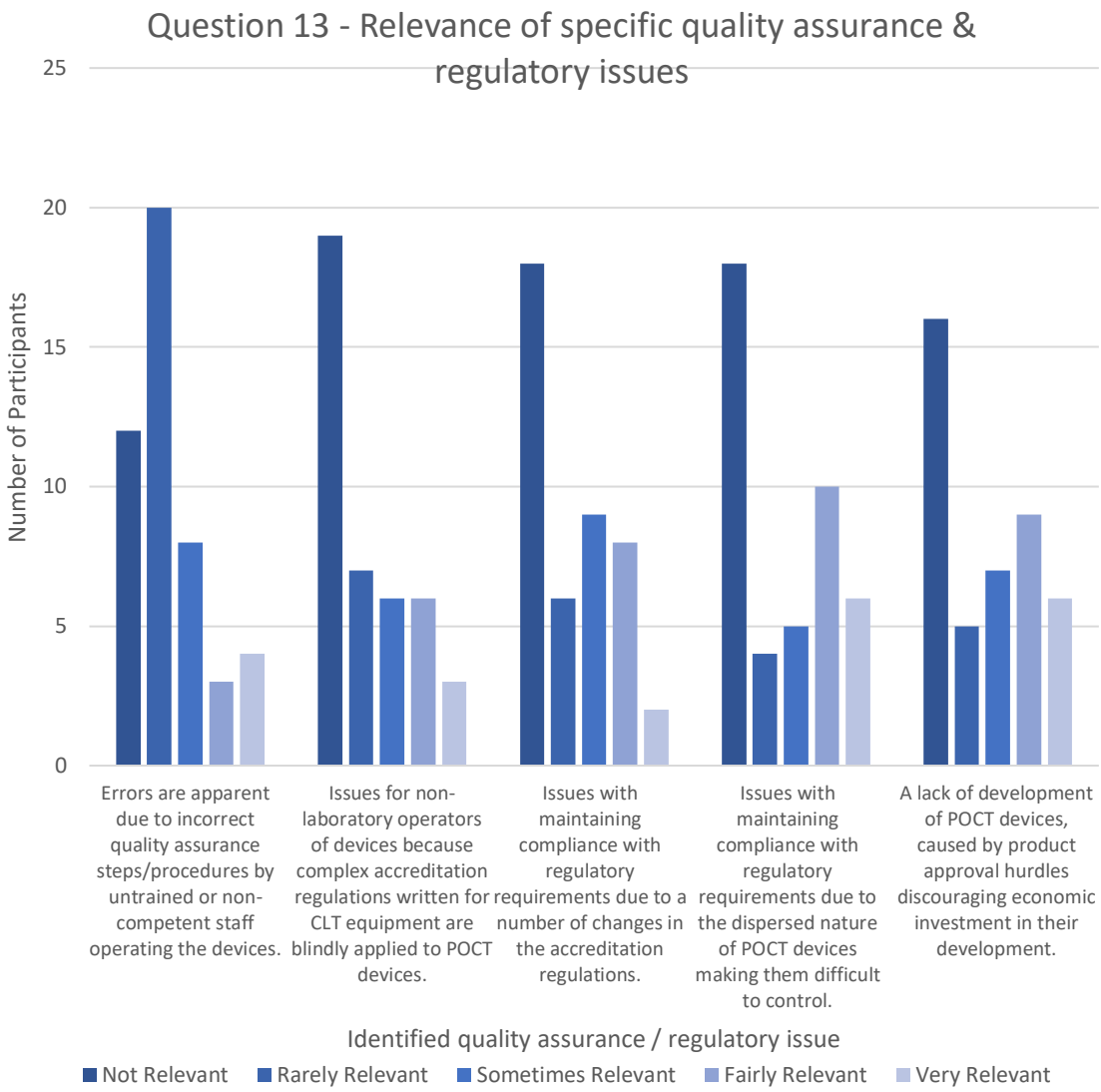

Figure 4.11 - Clinician opinion on relevance of specific quality assurance and regulatory issues within their own clinical institution (n=48).

It can be seen in 4 of the 5 areas addressed here, i.e. all but that regarding use of devices by untrained or non-competent staff, that the dominant response was that these issues were not relevant within participant's place of work. Although this may genuinely be the case, it may also be worth considering that the apparent lack of knowledge by senior clinicians in these areas contributes to their lack of awareness towards any such issues that may actually exist in reality. The single issue here that did not receive a dominant "not relevant" response was that regarding the use of devices by non-competent or untrained staff and the resulting errors that can result from such actions. From the responses recorded it can be seen that this particular issue is rarely relevant within the surveyed hospitals and/or Health Trusts, indicating perhaps that this does happen. However, quality assurance issues with respect to diagnostic tests can have serious consequences and even a rare occurrence may have unacceptable consequences in terms of patient management and welfare. One consultant who commented further added *"this is*

infrequent but can be very important, if we have 300 patients a day and one gets a wrong result then it could be very serious".

4.3.3 Device Performance & Data Management Issues

Device performance and data management issues formed the third most prevalent category of barrier that was highlighted by the systematic literature review study, as reported in Chapter 3. Within this category, an issue that was commonly identified in the reviewed literature was that of the perceived reduced level of analytical performance that POCT provides in comparison to CLT. Figure 4.12 outlines the clinical opinion obtained from this primary UK clinician survey with respect to the level of analytical performance of POCT and shows clearly that there is strong agreement between the majority participants that the level of performance is adequate, thereby contradicting the indication given by literature. Indeed, 46% of study participants regarded the performance of POCT devices as "high", while a further 37% rated them as having "very high" performance in comparison to CLT instruments. No clinicians regarded the analytical performance of POCT devices as being "very low", and only one of the 48 gave a "low" response. The final 15% of participants gave a response in the "neutral" area of the ranking scale.

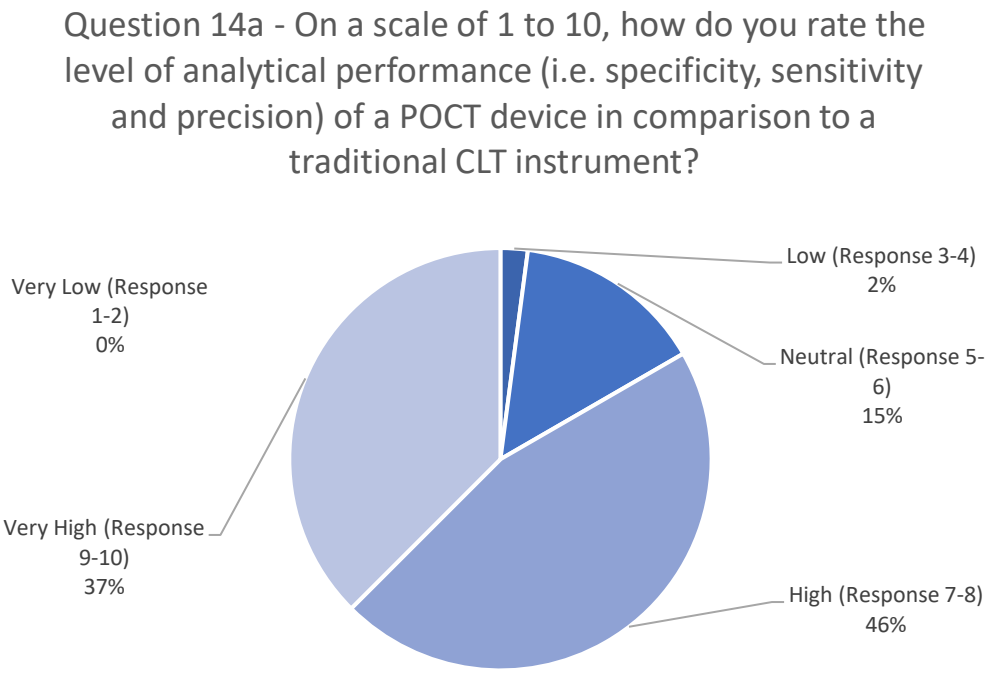

Figure 4.12 - Clinician opinion on the level of analytic performance of POCT devices (n=48).

The general consensus amongst the UK NHS clinical consultants interviewed was that the level of performance provided by the CLT service was absolutely the gold standard but that it was often significantly above and beyond the actual clinical requirement at the time of the test. Therefore, although it is recognised that the core diagnostic power of POCT devices cannot

match that of the technology offered by the central laboratory, their level of performance is high enough to be clinically acceptable. The slight variability in opinion of respondents is deemed to be due to the fact that the level of analytical performance of POCT devices depends heavily on the nature of the test, i.e. whereas the more embedded and clinically accepted POCT tests such as blood gas tests offer excellent analytical performance, some other tests such as D-dimer and troponin can provide either conflicting results or a less sensitive result in comparison to the equivalent CLT output and are therefore seen as being clinically inferior. Other interesting comments by interviewees include:

- *"There is some variation between POCT and CLT but this is accepted, POCT has limitations which the user must be aware of. POCT devices are used with very specific cut-off values so results can sometimes fall into grey areas."*
- *"A lot of POCT devices measure different parameters to the lab and so they are not comparable. It would be desirable to be able to perform tests using both POCT and CLT and combine the results to build a more complete picture."*

Another perceived concern that was identified from the literature review is the lack of connectivity of POCT devices to central healthcare systems and patient records. Figure 4.13 outlines that clinical opinion collated from within this study on this issue and indicates that, in general, the connectivity and data management capabilities of a POCT system do indeed tend to be significantly poorer in comparison to the system utilised by the central laboratory service. Some 17 of 48 participants (36%) indicated that connectivity and data management were "very poor" while 16 participants (33%) indicated that they were "poor". Comparatively, just 8% of participants indicated a "neutral" response here and only 6% gave a response indicating that connectivity and data management of POCT was "good". Although, 17% (8 of 48 clinicians) did regard these attributes as being "very good" for POCT, the comments made by participants indicated a commonly held opinion that there was often no direct data entry available through the use of POCT, and that results therefore had to either be hand-written or printed and attached manually to physical patient records. There are clearly a number of potential problems stemming from this finding that are related to the clinical management of patients; for example, clinicians may be unable to look up previous test results for comparison, and likewise the results of tests carried out in one department may not be visible within another leading to the duplication of the tests being carried out. However, difficulties with connectivity does not necessarily mean that solutions are not available and POCT manufacturers will often provide an exclusive interface for their range of products. One consultant interviewed commented regarding this aspect thus: *"Connectivity is possible but usually there is a big cost. POCT connectivity is very fragmented while central lab instruments all tend to work under one*

interface. There is a big need for a single IT system that controls all POCT systems but still provides the full functionality of the individual interfaces."

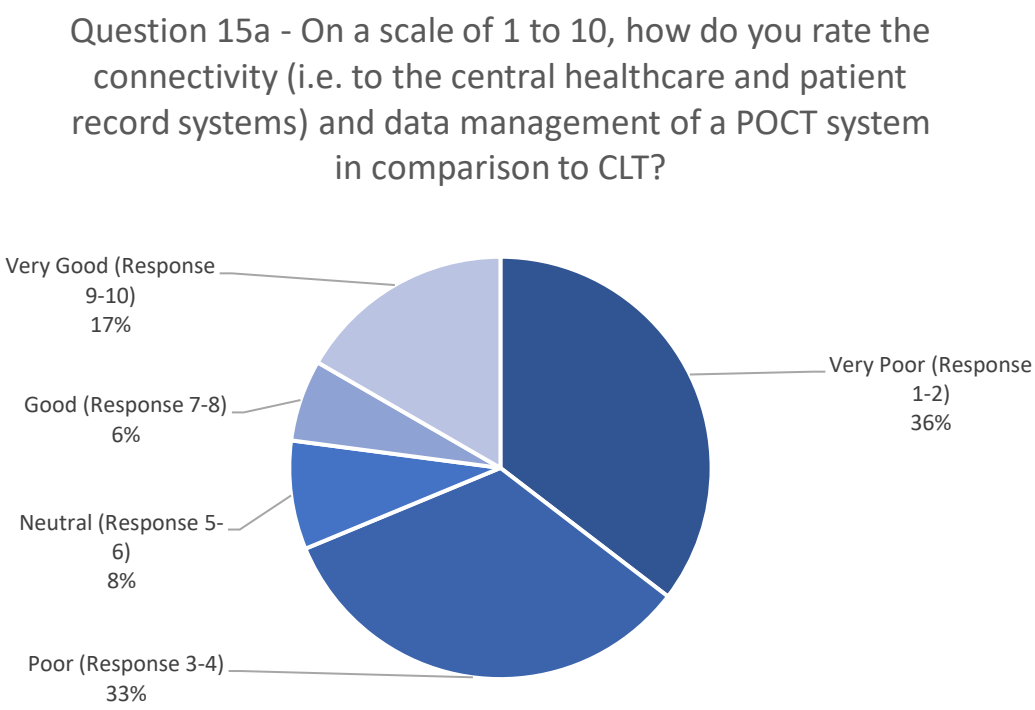

Figure 4.13 - Clinician opinion on the connectivity and data management capabilities of a POCT system (n=48).

Although, it would appear that POCT connectivity and data management is not at the same level as that of the central laboratory provision, this does not translate necessarily into problems with everyday usage regarding the deduction of a timely and reliable diagnosis. Of the 33 respondents who rated the connectivity and data management as "poor" or "very poor", 25 suggested that this does not make it more difficult to make a timely and reliable diagnosis when compared to utilising test data from the central laboratory system. The consensus is that in the experience of many users, POCT was employed mainly in time-critical situations in order to make a quick clinical decision, where trends are typically not as important and hence there is little value in looking back at previous test results. Therefore, simply from a diagnostic point of view, this lack of connectivity and the lack of ability to maintain up-to-date test data within the patient records does not affect patient management as much as might have been expected.

A further impediment identified from the literature was the usability of the devices and specifically some inherent difficulties in performing the actual tests within the near-patient clinical setting. However, as outlined in Figure 4.14, participants within this study have indicated that the usability of POCT devices is generally straightforward and that no major issues with usability exist. Some 70% of respondents rated the use of POCT devices as being "very easy",

with a further 13% regarding them as “easy” with respect to their answers given on the 10-point scale. No participants in the study deemed the use of POCT devices to be “very difficult”. Just 5 of 47 responses (11%) to this question were in the “difficult” segment of the scale, while the remaining 6% were given as “neutral” responses.

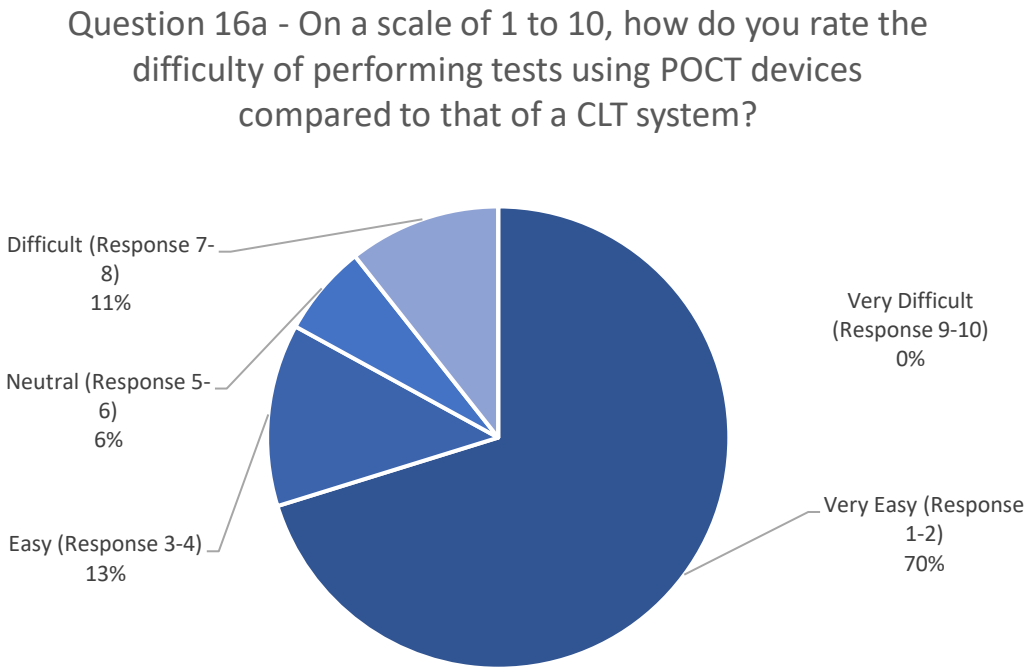

Figure 4.14 - Clinician opinion on the difficulty of performing tests using POCT devices (n=47).

One consultant interviewed added that *“there may be pitfalls however because the use of the devices seems so easy; training is still required”*. Of the 5 respondents who indicated that the use of such devices was difficult, 1 suggested that the only way to overcome such difficulty was through the placement of dedicated staff in the clinic by the central laboratory service to operate the devices throughout the respective Health Trust or hospital.

With regard to the relevance of specific device performance and data management issues, study participants were questioned on a number of aspects with the responses shown in Figure 4.15. It can be seen that 2 specific issues are generally seen by clinicians as having “low” relevance namely; devices producing a reduced analytical performance in comparison to CLT instruments and operators encountering difficulties with use of POCT devices. Some 71% of respondents indicated that a reduced analytical performance was of either “no” or “low” relevance in their place of work. Responses here echoed the earlier sentiment that although POCT was not as analytically capable as CLT, it was still clinically acceptable. Additionally, 61% of respondents indicated that device usability problems were also of “no” or “low” relevance in their respective hospital or Health Trust. Moreover, they indicated that in many cases the only difficulties with

the use of POCT stemmed from a lack of familiarity with the device or when the operator has not used a particular device in a while. One consultant added here that *"overcoming a lack of familiarity is down to the quality of both training and SOP (standard operating procedures) in place within the institution"*. The most varied response here was with respect to issues caused by poor connectivity to central healthcare and patient record systems. The variation in opinion on relevance of data management issues would suggest that although the poor connectivity does not affect the ability to reach a diagnosis in the immediate short term (as stated in clinician responses to Question 15), some other data management issues are apparent. Two clinicians commented here that archived information and permanent records are important, and hence the use of POCT inhibits the ability of the respective Health Trust to maintain patient records which may be valuable at a later date with respect to ongoing treatment or reviews.

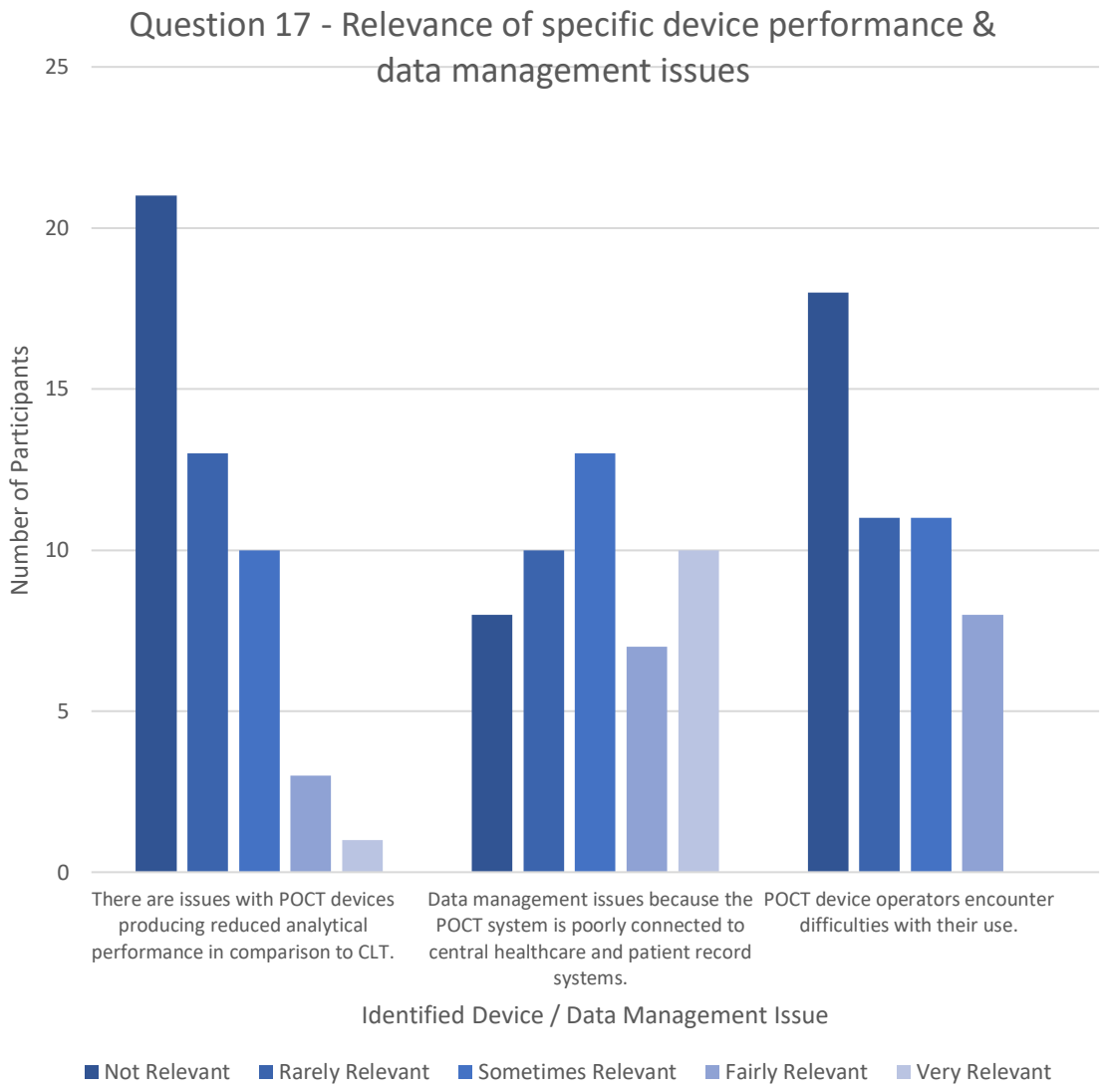

Figure 4.15 - Clinician opinion on relevance of specific device performance and data management issues within their own clinical institution (n=48).

4.3.4 Staff & Operational Issues

The fourth category of impediment to the uptake of POCT highlighted identified within the relevant literature is that associated with staff and operational issues. Participants in the survey were asked to give their opinion as to the impact of POCT upon the workload of those operating the devices. As shown in Figure 4.16, 18 of the 48 respondents (38%) "strongly disagreed" with the assertion that POCT significantly increased the workload of front line clinical staff, while a further 13 respondents (27%) gave an answer indicating "disagreement". Another 15% of participants gave a "neutral" response while a total of 20% of participants gave an answer in the "agree" and "strongly agree" categories combined. It can therefore be seen that there is significant disagreement with the notion of increased workload due to the operation of POCT devices. Justification of this opinion by the clinical knowledge base can be ascertained from the comments given by consultants interviewed in person as part of the study:

- *"It's more time consuming to send a sample to the lab; filling out forms, filling samples, chasing results etc."*
- *"POCT actually alleviates workload; there are less forms, less labels and less chasing the lab for results."*
- *"POCT reduces workload as you don't have to chase the lab for results."*
- *"It takes longer for a nurse to take a blood sample and chase the lab for a result."*
- *"Chasing the laboratory for results is more work than using POCT."*

It should be noted here that there is significant information to indicate that the more immediate nature of test results offered by POCT actually alleviates the workload of front line clinical staff by eliminating the need to "chase up" results from the central laboratory. Of the 10 respondents who had the opinion that POCT significantly increases the workload of device operators (answering in either the "agree" or "strongly agree" areas of the ten-point rating scale), 7 believed that this did not lead to a reduction of staff satisfaction. Comments from these respondents included *"staff satisfaction actually increases due to instant results"* and *"the advantages of using POCT outweigh the extra workload and staff understand this"*.

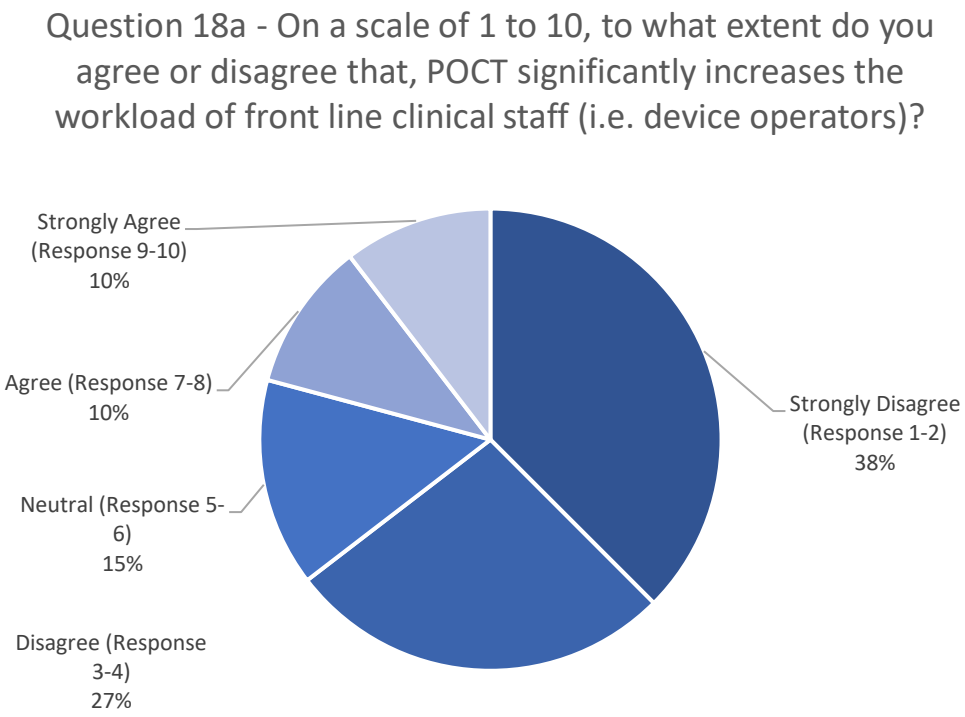

Figure 4.16 - Clinician opinion of the impact of POCT upon the workload of device operators (n=48).

A further issue that was identified from the literature study is that of the apparent reluctance of the CLT service to release the control of diagnostic testing to other cohorts within the respective hospital or Health Trust. In this respect, clinical opinion was significantly varied with regards to how true this particular issue is in reality, as outlined by Figure 4.17. Opinion on this particular issue is divided fairly uniformly across the scale, with 21% of participants "strongly disagreeing", 15% "disagreeing", 19% "agreeing" and 15% "strongly agreeing" with this statement. The highest response area was that of a "neutral" response, provided by 14 of 47 respondents (30%).

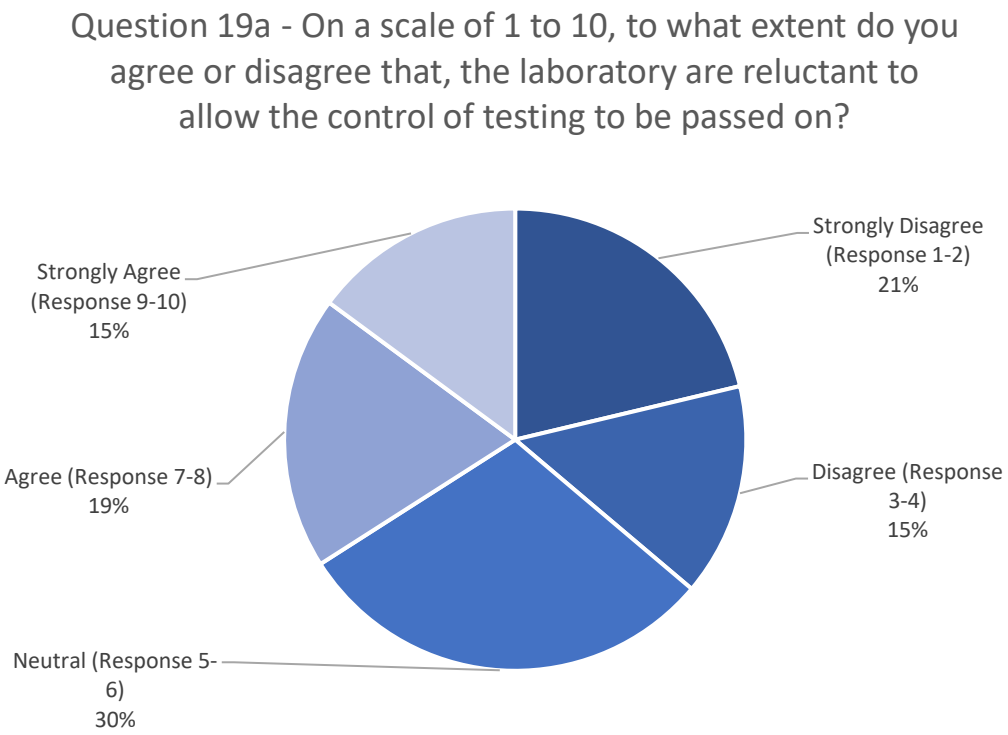

Figure 4.17 - Clinician opinion of the reluctant of the central laboratory to release the control of testing (n=47).

Comments from those "disagreeing" or "strongly disagreeing" with this statement include:

- *"The laboratory is happy to release control as long as testing is carried out correctly."*
- *"POCT will always be seen as a threat to the laboratory, but laboratory workloads are increasing and the movement of POCT out to the wards is cushioning this."*
- *"POCT is actually a burden on the laboratory staff, it would make it a lot easier for the lab if control was passed on."*
- Conversely, those who "agree" or "strongly agree" with the statement commented that:
- *"The lab is paranoid about POCT, there is no trust in the devices."*
- *"The lab is very sceptical about POCT; a lack of governance caused these issues."*
- *"There is a reluctance but this is understandable; that is their governance role. They are understaffed and need dedicated staff to look after POCT, which makes it hard for me to get the devices I want."*

Importantly, of the 16 respondents who indicated there was indeed a reluctance by the central laboratory to release the control of diagnostic testing (giving responses to Question 19a in the "agree" or "strongly agree" areas of the 10-point scale), 13 believed that this acted as an impediment to the more widespread adoption of POCT within the clinical environment. Interestingly, 1 consultant interviewed added here that the reluctance was not apparent for all types of POCT, and that the central laboratory were happy to release control of testing for blood

gases and blood sugars to other areas of the institution simply because of the volume of tests required was so high.

Participants in the study were asked to give their opinion as to how adequately the clinical care pathway and role of the central laboratory have been altered to incorporate the use of POCT. Responses to this question are outlined in Figure 4.18. The most frequent response here was in the "agree" category, i.e. that the pathways and role of the central lab had indeed been altered sufficiently, with 34% of the response given in this area. A further 21% of participants "strongly agreed" with this notion, while 26% gave a "neutral" response. Notably, the response levels were low in "disagree", just 6 of 47 (13%) respondents indicating that this was the case, while a further 3 "strongly disagreed" (6%). Hence, this particular issue is not seen to be a major concern to this clinical group in reality. However, it should be noted that this was the second question that was found as having a disconnect in the response distribution between the 2 strands of the study (face-to-face and electronic submission) that was used to appropriately amalgamate the data. Whereas the face-to-face responses resulted in 73% of participants being in the "agree" or "strongly agree" category for this statement, the online responses were much more varied, with 48% of participants indicating a "neutral" opinion on the subject. It is possible that the wording of the question, which included 2 different aspects for consideration, i.e. both the clinical care pathway and role of the central laboratory, may have led to the more varied opinions offered by the online respondents whilst the face-to-face participants had the opportunity to clarify this appropriately. Hence, in an electronic setting, respondents may have been more likely to indicate a neutral opinion.

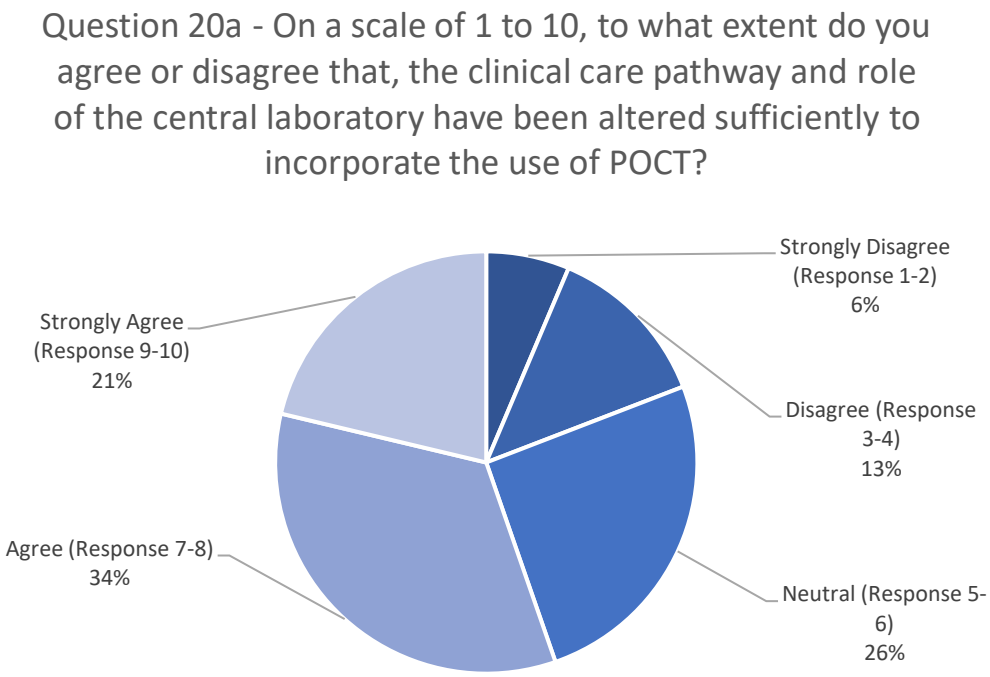

Figure 4.18 - Clinician opinion of how adequately the clinical care pathway and role of the central laboratory have been altered to incorporate POCT (n=47).

Notwithstanding the possibility for confusion, more than half of the respondents here "agree" that the clinical care pathway and role of the central laboratory have been altered sufficiently to incorporate the use of POCT. Some interesting comments from interviewed participants in this regard include:

- *"NICE guidelines now include POCT."*
- *"The clinical care pathway is evolving all the time in order to control the introduction of POCT".*
- *"Some pathways have been altered sufficiently, however there are still a number that throw in the use of POCT with very little thought."*

It should be noted that of the 9 respondents who indicated that there was poor accommodation for POCT within clinical care pathway (by "disagreeing" or "strongly disagreeing" with the statement), 6 believed this did not affect the ability to make a timely and reliable diagnosis using POCT in comparison to CLT.

By way of an assessment of the relevance of specific staff and operational issues that were found within the academic literature, participants were questioned on 6 key areas, as highlighted in Figure 4.19. These issues are specifically; reduced staff satisfaction levels and increased friction between clinical staff groups due to the use of POCT; impeded uptake of POCT caused by the reluctance of the central laboratory service to release the control of diagnostic testing; inappropriate use of POCT, including over-use and reliance on test results; benefits of POCT being negated due to a requirement for clinical care pathways and role of the central lab to be altered sufficiently; POCT system running inefficiently due to the requirement for an interdepartmental management structure with clear clinical governance for POCT, and; difficulties implementing POCT due to a reluctance to change within healthcare bodies along with a lack of evidence justifying POCT. Four of these 6 issues were seen as having a dominant "not relevant" response by participants within this study. Reduced staff satisfaction and friction between staff groups that occur as a result of the utilisation of POCT are not seen as being relevant issues within the UK hospitals and Health Trusts included in this research, with 76% of respondents indicating these as having "no" or "rare" relevance. Furthermore, 50% of respondents indicated that the resistance of the central laboratory to release control of testing was either "not relevant" or "rarely relevant" in terms of impeding the more widespread adoption of POCT within their clinical place of work (23% of participants indicated this issue was sometimes relevant). A total of 67% of respondents indicated that alterations to clinical care pathways and the role of the central laboratory were either "not relevant" or "rarely relevant". Additionally, 57% of participants believe that there is "no relevance" or "little relevance" with regard to the requirement of an interdepartmental management structure with clear clinical

governance for POCT, with 1 consultant commenting that testing accreditation for POCT nullifies this problem within their Health Trust.

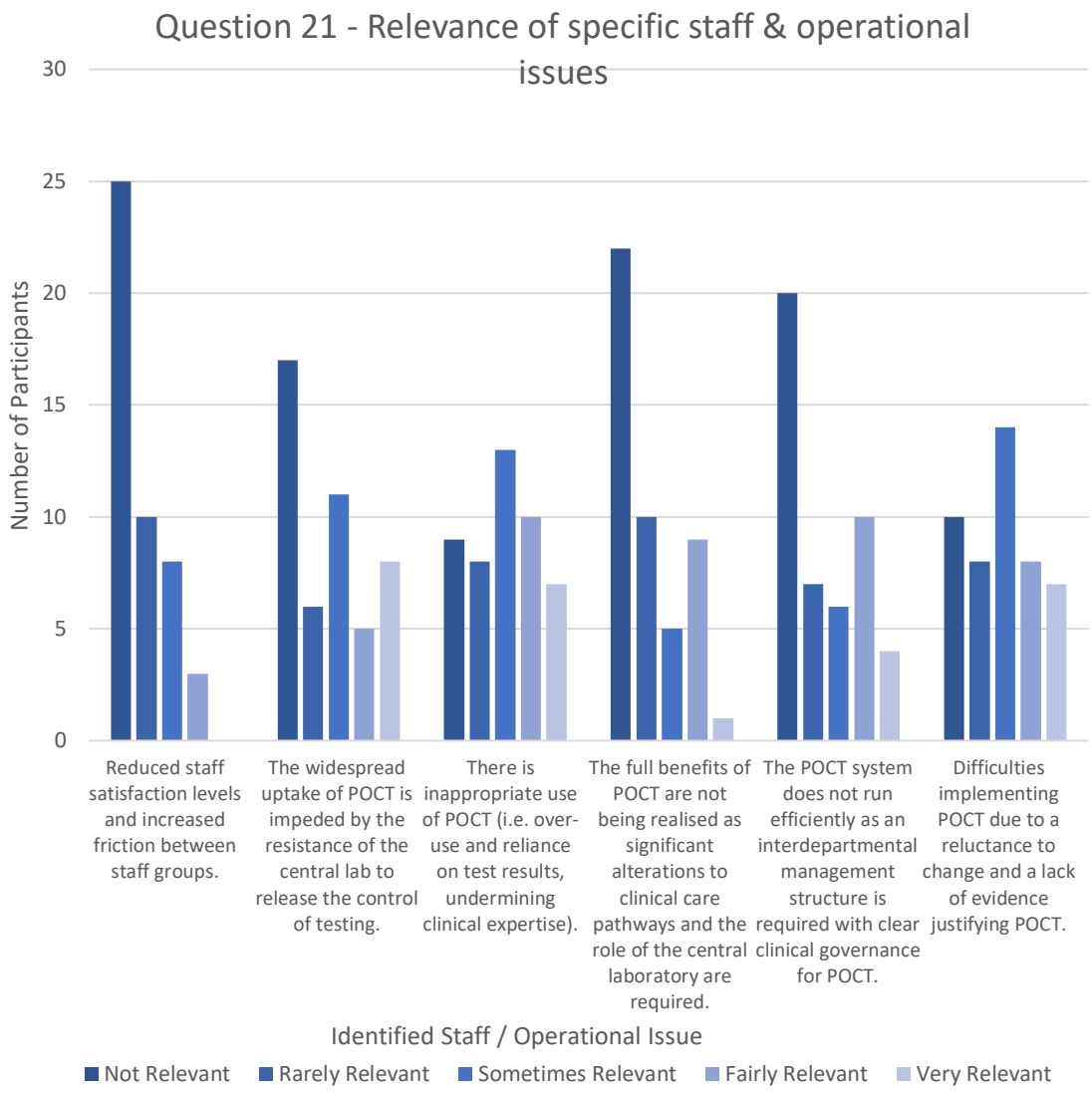

Figure 4.19 - Clinician opinion of relevance of specific staff and operational issues within their own clinical institution (n=48).

The remaining 2 issues displayed much more varied responses and the most frequent response to each was in the "sometimes relevant" category, although this would not be considered a significant majority in either case (27% of responses for inappropriate use of POCT and 31% of responses for reluctance to change and a lack of evidence). Inappropriate use of POCT saw much disagreement, comments from interviewed consultants include the following:

- *"POCT enhances the clinical picture but sometimes tests are carried out and results are ignored."*
- *"There is overuse due to the appropriate pathways not being in place."*
- *"POCT is often used simply as a delay tactic to buy more time before a decision is made."*

- *"Yes, but overuse in terms of results does not affect patient management."*
- *"There is a lack of application of clinical skills, but this can be said for all blood tests, not just POCT."*

Opinion was also very much divided with respect to any difficulties encountered with implementing POCT due to general reluctance to change within the health system and a lack of evidence justifying the use of POCT. Some participant comments in the response to this issue include:

- *"There is a lot of enthusiasm for POCT and companies are spending a fortune on development and the associated evidence of usefulness."*
- *"There is a lot of evidence coming out for POCT, the issue is proving it will be used regularly enough to justify it."*
- *"There is lots of evidence now, the issue is funding the service."*
- *"Not so much reluctance but the evidence isn't great, POCT always lags behind the lab in terms of development."*
- *"Not as much reluctance but there is a lack of evidence and understanding of the benefits of quicker results."*

4.3.5 Other General Issues

In addition to the highly-specified aspects of the survey tool, participants were also questioned more generally with respect to their opinion of the real value of POCT. This final part of the study gave an opportunity for free response by the respondents. Firstly, participants were asked to indicate the main advantages that POCT offered in comparison to CLT. The responses provided are summarised in order of frequency as follows:

- Rapid turnaround time (TAT), resulting in a quicker decision/diagnosis and earlier clinical intervention (96% of respondents).
- More efficient patient management (27% of respondents).
- Improved patient/operator satisfaction and convenience (27% of respondents).
- Improved quality of care and better patient outcomes (18% of respondents).
- Avoids sample transfer where there is no laboratory on site or within close proximity (9% of respondents).
- Ease of use (7% of respondents).
- Helps meet political targets i.e. TAT targets and patient waiting times (4% of respondents).
- Provides the ability to the clinician to repeat tests (4% of respondents).
- Less reliance on a chain of services where delays are more likely (4% of respondents).

- Cost savings (4% of respondents).
- Reliability and accuracy (4% of respondents).
- POCT provides a good backup service when laboratory or sample transport systems are down (individual response).
- Avoids sample stability issues during transport (individual response).
- Transfers some of the laboratory workload to the wards (individual response).
- Provides control of when the sample is tested to the clinician and the opportunity to perform serial testing (individual response).
- Overcomes issues with bad access to hospital services (individual response).

Clearly, the overwhelming response was that of a rapid TAT, resulting in a quicker decision/diagnosis and earlier clinical intervention, which was indicated by 96% of participants in this study. Efficiency in patient management and patient/operator satisfaction and convenience are also both significant at 27% each.

Similarly, participants were questioned with regard to the main disadvantages of using POCT in comparison to CLT. The responses are summarised as follows in order of frequency as follows:

- Increased cost (31% of respondents).
- Poor quality / inaccuracy of result obtained by untrained or non-competent staff and the consequent risk to the safety of the patient (31% of respondents).
- Lack of connectivity to central healthcare and patient record systems (22% of respondents).
- Quality management requires significant resources and is difficult to control due to dispersed nature (20% of respondents).
- Staff training requires a lot of time (20% of respondents).
- Reduced accuracy compared to CLT and duplication of tests carried out by the central laboratory (18% of respondents).
- Difficulty in ensuring continued staff competency and unfamiliarity caused by a lack of regular use (13% of respondents).
- Inappropriate use i.e. over-use and reliance on results undermining clinical expertise (11% of respondents).
- Results and subsequent interpretation highly dependent on operator competency (11% of respondents).
- Takes up a lot of staff time (11% of respondents).
- Auditing and clinical governance is difficult due to fragmentation of the service; lines of accountability are very unclear (7% of respondents).

- Requires awareness of limitations otherwise use is dangerous (4% of respondents).
- Little support from senior management for POCT (4% of respondents).
- Lack of a specific budget for POCT (individual response).
- Financial benefits are difficult to prove despite an improvement in patient care (individual response).
- Sufficient skills are required to perform POCT and so it may not be a 24-hour service (individual response).
- Added responsibility on another healthcare professional with regards to calibration, ordering test strips etc. (individual response).
- Maintenance of devices is difficult (individual response).
- Devices are less reliable in terms of breaking down (individual response).
- Lack of troubleshooting help when devices break down (individual response).
- POCT not widely available in all institutions (individual response).

In this case, it is the increased cost of POCT and the poor quality/inaccuracy of the results obtained by untrained or non-competent staff (and the consequent risk to the safety of patients) that are the 2 disadvantages that appeared as the most common, being indicated by 31% of respondents for each.

With respect to the clinical value of POCT, participants in the study were further asked to give their opinion on which diseases and/or conditions benefitted most from the use of POCT. The responses from this consideration of clinical opinion are summarised in order of frequency as follows:

- Respiratory conditions i.e. blood gas testing (67% of respondents).
- Diabetes i.e. blood glucose testing (67% of respondents).
- Blood coagulation, i.e. International Normalised Ratio (INR) monitoring (42% of respondents).
- Cardiac conditions, i.e. cardiac marker testing (29% of respondents).
- Sepsis testing (29% of respondents).
- Urine pregnancy testing, i.e. in ED or surgery (18% of respondents).
- Other blood tests, i.e. HBA1C, lactate etc. (18% of respondents).
- Monitoring of foetus condition during pregnancy (16% of respondents).
- General trauma and internal bleeding, i.e. emergency conditions (13% of respondents).
- Drug addict patients, (11% of respondents).
- Brain injury and critical care patients, i.e. ventilated (7% of respondents).
- Gastroenterology (individual response).

- Patients with mental health issues (individual response).
- General surgery (individual response).
- Hypotensive patients (individual response).
- Influenza (individual response).
- Infectious diseases in developing countries (individual response).

Respiratory conditions (i.e. blood gases) and diabetes (i.e. blood glucose monitoring) were found to be the 2 most prominent diseases served by POCT here, both having been cited in responses by 67% of study respondents.

In order to further satisfy the solutions-based approach undertaken in this research, participants were asked to provide suggestions as to how any of the real or perceived barriers to the adoption of POCT technologies could be overcome. The responses obtained according to frequency are as follows:

- Audit the use of POCT to provide evidence of clinical and/or economic benefits to stake holders as a way to overcome issues such as mistrust of POCT and a lack of full backing for its implementation by the healthcare system (36% of respondents).
- Better connectivity to central healthcare systems and interfaces (27% of respondents).
- Improved training processes, including re-training and mandatory centralised training (24% of respondents).
- Reduced costs from manufacturers for both the devices and their implementation via a form of a central POCT funding (20% of respondents).
- Regional consensus/strategy on POCT procurement (18% of respondents).
- Increased laboratory support for implementation and after-care, i.e. dedicated team to look after QA in POCT (18% of respondents).
- Improved QA processes and auditing processes for POCT to ensure confidence in them (13% of respondents).
- Closer collaboration between the areas involved (11% of respondents).
- Treat the introduction of POCT tests in the same as that employed for the introduction of new drugs, i.e. through a proper change management project (4% of respondents).
- Increase availability of POCT though the system (4% of respondents).
- Increase use of POCT in primary care (individual response).
- Give feedback on POCT performance to stakeholders following implementation (individual response).
- Improve user-friendliness of devices (individual response).

- Adopt a more streamlined path from device development to clinical use (individual response).
- Manufacturers encouraged to provide free pilots of POCT systems so that benefits can be witnessed first-hand (individual response).
- Increased transparency of governance arrangements and expectations throughout the application process for such devices (individual response).
- Improvements to the sampling and analytical capabilities of the devices (individual response).
- Restrict the use of POCT to controlled environments, i.e. specialist clinics; based on the fact that 24-hour access machines are difficult to regulate and there are issues with ensuring the competency of operators (individual response).

The most common suggestion offered here was to audit the use of POCT in order to provide evidence to stakeholders of any clinical and/or economic benefits attainable in order to overcome issues such as laboratory mistrust and a lack of full backing by the full health system, as indicated by 36% of study respondents.

Considering the current impact on POCT adoption, the survey participants were asked to rank the 4 categories of issue identified from systematic literature review study (economic, quality assurance & regulatory, device performance & data management and staff & operational issues) on a scale of 1 to 4, with 1 being the most important in regard to POCT uptake and 4 being least. These data were managed using a tiered scoring system to accumulate the categories into a final ranking order, where a category would receive 4 points for a first-place ranking, 3 for a second-place ranking, 2 for a third-place ranking and 1 point for a fourth-place ranking. The scoring frequency of the resulting responses are provided in Figure 4.20. Using this scoring system, economic issues along with device performance and data management were both ranked as having the most current impact on POCT uptake within UK hospitals and Health Trusts, with a score of 123 each. The third most important category in this regard was found to be device and data management issues with a score of 105, with staff and operational issues placed as having least current impact on POCT uptake with a score of 99.

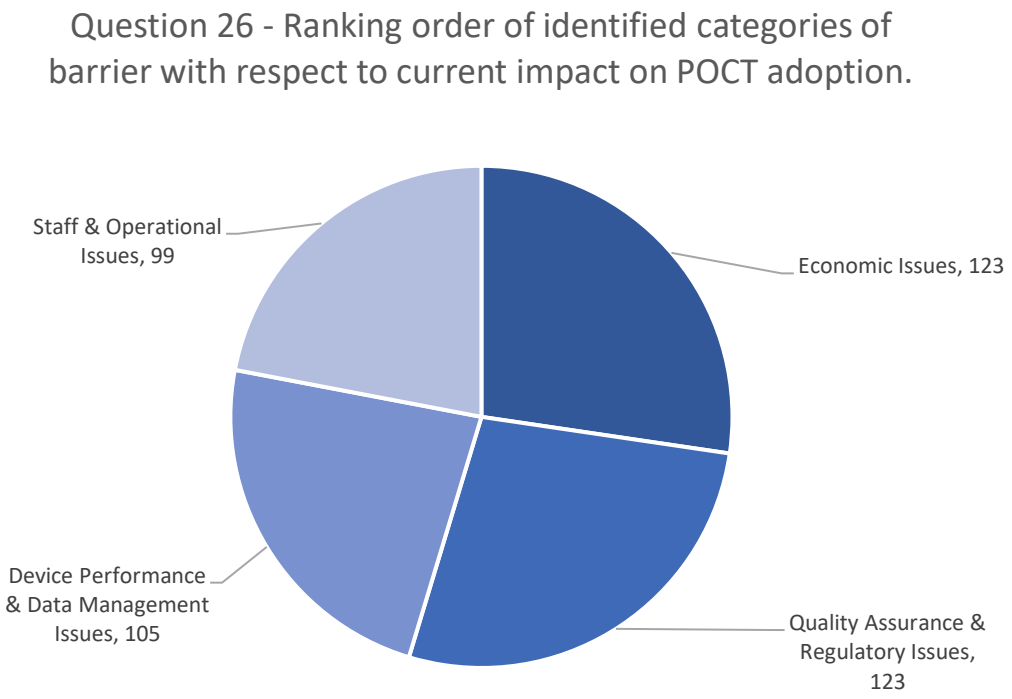

Figure 4.20 - Clinician opinion on the ranking of relevance of categories of barrier to adoption of POCT (n=45).

4.4 Discussion

The primary data collected herein is intended to test the validity of the findings from the systematic literature review reported in Chapter 3. The core objective is to determine which issues actually exist in reality for the adoption of POCT and what the significance of these are in clinical practice. The study group was chosen as a sample of the UK NHS which has been selected as an example of a healthcare system free at the point of delivery.

Interestingly, the ranking by study participants of the barrier to adoption categories in terms of current impact upon POCT uptake (Question 26) mirrors the findings from the systematic literature review study, in that economic issues along with quality assurance and regulatory issues were found as being the most prevalent categories cited in both the literature and within UK hospitals and Health Trusts. This clearly gives a strong indication of the significance and relevance of these categories in regard to improving the uptake of POCT.

Notwithstanding their obvious significance, it is important to consider these categories in finer detail in order to better understand the fundamental underlying issues. Focusing firstly on the economics of POCT, there is clear agreement amongst the majority of clinicians in this study that the cost per test is higher than that associated with CLT. It is also important to note that the majority of participants also suggested that the use of a POCT system is cost-effective. Therefore, the dilemma here is very much with respect to weighing up the increased costs

against the benefits to clinical care that POCT can bring, as confirmed by comments made by those interviewed in the face-to-face aspect of the study. If benefits to clinical care are apparent, then increased cost cannot be considered a barrier to uptake as improved care should always take precedence in a healthcare system free at the point of delivery such as the UK NHS. This is because this system must be run in a cost-effective manner. While reduced costs may bear a short-term economic advantage, the overall efficiency of the system will suffer. It has been demonstrated that the improved quality of care in the NHS results in overall cost savings through both quality-adjusted life years and reduced patient lengths of stay (Meacock, Kristensen et al. 2014). The issue arises when benefits to the quality of clinical care are not obvious and/or are difficult to measure adequately. There is expert opinion within the academic literature suggesting that, while POCT can provide longer term economic benefits (for example those attainable through a reduced length of stay for patients in hospital and reduced numbers of outpatient appointments), there is difficulty in placing a financial value on such gains attained over the longer timescale (St John 2010, Crook 2000). Accurately evaluating both the clinical and long-term economic value attainable through the use of POCT is necessary to overcome these particular perceived issues of increased cost. Attaining cost-effectiveness data was indicated to be problematic by a significant proportion of participants due to the apparent lack of a defined budget for POCT. In many cases, the financing of POCT comes out of one overall pot (i.e. a yearly budget for a department), making the measurement of their cost-effectiveness difficult. Procurement, reimbursement and budgeting were generally found to be areas of significant debate in this study with regard to accommodating the interdepartmental nature of POCT deployment. This variation in opinion is potentially due to the utilisation of POCT devices being different across the hospitals and Health Trusts considered as part of the study. A number of clinicians commented that the interdepartmental sharing of POCT devices was due to be stopped or had already been prohibited in their workplace due to cross-infection concerns. However, other consultants interviewed commented that access to the devices in their departments was often abused by other departments without any reimbursement for their use. It is therefore difficult to define the extent to which POCT devices are used as interdepartmental resources in reality. The concept of “silo budgeting” (of separate budgets for different departments) and current reimbursement methods have already been noted for their incompatibility with an interdepartmental technology such as POCT in the literature base reviewed in Chapter 3, with reimbursement being labelled “the final barrier to a significant POCT market” (Huckle 2006).

Consideration of specific economic barriers to POCT adoption within the hospitals and Health Trusts surveyed indicated that 3 issues were seen by approximately half of the participants as being of significant relevance within their place of work. Firstly, difficulties in justifying the

implementation of a POCT system due to the true cost-effectiveness of such a system being difficult to gauge and the direct cost comparison studies against traditional CLT methods being complex. Secondly, difficulties due to the relatively high initial implementation costs. Thirdly, difficulties associated with the higher cost per test of POCT in comparison to CLT. Although this evidence may not be enough to suggest that these issues are endemic across all clinical areas in the UK NHS, clearly there are certainly pockets within the surveyed Health Trusts where they are seen as being highly relevant. Variation in responses with respect to economic issues does not appear to follow any pattern based on clinical specialty and it is likely that these economic issues are the product of specific budgeting and procurement implementation within individual hospitals and Health Trusts. When analysing the economic issues, it is clear that there is significant debate regarding the true value of POCT with regard to assessing the increased cost versus the possible clinical benefits that this type of near patient of testing can bring. In Northern Ireland (as in the rest of the UK) health services are continuing to experience reduced funding, therefore the economic impact of all services will always be highly scrutinised. As such, the cost of new technologies is a major consideration in the process of adoption along with the complexity and scale of the technology, in addition to aspects such as; trialability; consistency with existing values; previous experiences of stakeholders and user needs/requirements (Llewellyn, Procter et al. 2014). However, common themes were relayed by respondents that could be used to further understand and overcome the issues surrounding costs and economics. Firstly, the requirement for a centralised POCT budget is clear, and would allow greater control of POCT spending, leading to increased transparency of the process which would then allow for a more accurate understanding of the cost-effectiveness realised through POCT use. Secondly, a significant proportion of respondents have indicated that there needs to be centralised procurement and a more clearly defined purchasing strategy for POCT and that this would allow for a more efficient use of devices within clinical institutions. It is apparent that individual departments are commonly purchasing their own devices but that these are not used frequently enough to justify the costs involved. A more centralised procurement process would allow devices to be purchased and utilised on a joint basis between departments with the attendant benefits this brings. Thirdly, based on this study, it is clear that there is a lack of strong evidence on clinical outcome improvements that POCT can provide which are needed to convince stakeholders that the benefits from such devices justify the cost of their implementation. The lack of evidence and literature on cost-effectiveness is not limited to POCT alone, yet is a characteristic of the diagnostic sector as a whole within healthcare delivery. This is a consequence of the traditional model of reimbursement strategy employed in laboratory medicine, based upon the complexity of test as a function of delivery as a cost-per-test service, hence discouraging the development of an appropriate evidence base (St John, Price 2013). In

summary, although economic issues impact upon the uptake of POCT, much of this is a reflection of the nature of the current financial environment within UK healthcare system, rather than any specific characteristics of the POCT devices themselves. This type of testing, although more expensive than CLT, is nonetheless deemed to be cost-effective by healthcare professionals and so emphasis should be placed on providing the evidence of the clinical benefits that justify any increased costs at the outset.

Similarly, when considering quality assurance and regulatory issues relating to POCT use, several important points are noted. Firstly, it is apparent from a significant number of responses that the decentralised nature of the devices gives rise to increased opportunity for their use by untrained or non-competent staff. Further analysis with respect to the demographics of participant responses indicates that those from the clinical biosciences speciality (n=7) gave an average response of 9.5 on the 10-point scale used, indicating strong agreement that this was the case. However, by comparison, respondents from general medicine (n=7) averaged a response of 3.6 on the same scale, indicating significant disagreement. Hence, a clear disconnect in opinion is recognised between those clinicians who are essentially responsible for the quality of testing within their respective hospital or Health Trust, and those who actually utilise the POCT devices for patient care. The perspective of those most associated with the central laboratory is perhaps understandable, quality within this area is dependent on a small number of highly skilled individuals operating sophisticated instruments who are the direct responsibility of the central laboratory service. Conversely, quality for POCT is dependent on a large number of analytically unskilled individuals operating smaller, less sophisticated devices, who are not part of the personal management structure of the central laboratory. Such quality issues are not limited to untrained individuals specifically, but rather there are a number of concerns by the central laboratory regarding the use of devices by clinical staff, namely; the integration of daily quality control procedures into an already hectic role; device maintenance and troubleshooting, and; an impact on workflow within the respective clinical unit. Expert opinion has suggested that this can be overcome through the operation of POCT by laboratory personnel within the clinical units via the implementation of satellite laboratories (Shaw 2016). It has been demonstrated that, despite POCT users undertaking comprehensive training, operators were often unwilling or unable to carry out simple tasks with POCT, due to infrequent errors in the experience of the user and unfamiliarity with devices (O'Kane, McManus et al. 2011). The suggestion provided once more is that the increased support for POCT by staff from the central laboratory could be a solution to overcoming these concerns.

Regulatory requirements, imposed in an attempt to ensure quality, were also raised as an area of concern in the literature study. Specifically, managing a POCT system to maintain such

regulatory requirements has been cited as a possible impediment to their wider uptake (Lee-Lewandrowski, Lewandrowski 2001). These issues relate to a number of areas including; the dispersed nature of the devices making them difficult to ensure compliance, a lack of knowledge by clinicians on the exact specifics of the regulatory requirements and the regulatory requirements for POCT being overly complex. It was apparent from responses in this area of the study that a lack of knowledge does indeed exist, 6 clinicians did not respond to this particular question due to a lack of knowledge and a strong variation in responses overall was noted. Increased education on the regulatory requirements must be delivered to clinicians involved with POCT, difficulties arise when central laboratory personnel (who have knowledge of the regulatory requirements) are expected to ensure compliance for a dispersed system of devices that other clinical cohorts utilise on a day-to-day basis. Furthermore, while the evidence base for internal quality control has been increasing with respect to CLT, literature with respect to POCT is very limited, leading to wide variation on what is considered to be acceptable quality control practice in this regard (Holt, Freedman 2016). Considering the complexity of requirements, participant response indicated that the regulations were complicated, however there is also an acceptance of the requirement to ensure quality assurance matches that of the central laboratory. Therefore, this situation is accepted to ensure quality. For example, if the regulations for the laboratory are complex then POCT regulations must match this regardless of their uniqueness. It is clear that in order to ensure compliance with regulations there must be a link between those who are responsible for testing quality, i.e. the central laboratory and the clinical groups that utilise POCT devices.

Levels of operator training and general support for POCT by the central laboratory showed no strong trend according to results of this study. A more detailed analysis and consideration of comments made by face-to-face responders in this study indicates that poor levels of support by the central laboratory are not necessarily considered to be a barrier to the uptake of POCT. Of the respondents that stated that the level of support and training that they had received from the central laboratory was low, the majority suggested that this was due to the fact that much of the training (and support) is actually provided by the device manufacturers themselves. This direct support was overseen by the central laboratory service, an arrangement that the clinicians are, in general terms, very satisfied with.

Consideration of the specific quality-related barriers to POCT adoption within the hospitals and Health Trusts surveyed via Question 13 found that the majority of study participants found these issues not to be relevant or to be rarely relevant. The consensus amongst these clinicians was that, although potentially errors could happen through the use of POCT, adequate controls were in place to prevent them from happening within their areas of practice. It should be noted that

even if errors are very small (in terms of a percentage of the number of tests completed), this could still be catastrophic with respect to the provision of patient care and wellbeing. A disconnect has been noted here between the opinions of those clinicians who work in clinical biosciences and those in other areas of hospital-based care in that the former are of the opinion that quality issues are more of a significant impediment to POCT use than those who actually use the tests as a diagnostic tool.

With respect to overcoming any quality related issues, 2 common themes were apparent. Firstly, provision of improved training processes would help to overcome the significant impediment associated with devices being operated by untrained or non-competent staff. Even if untrained or non-competent staff do not operate devices in a particular institution, there have been suggestions by study participants that the fear of this problem is enough to introduce a lack of trust, leading to reluctance from the central laboratory to promote decentralised testing. These attributes that healthcare technologies acquire through the course of often contested deliberations regarding adoption have been termed “technology identities” and have been recognised as being an explanation for non-adoption of POCT (Peirce, Faulkner et al. 2015). One potential way of implementing improved training processes would be to introduce mandatory centralised (regional) training for POCT use, much in the same way that training for blood transfusions is managed. The second common solution involves improved quality assurance processes and auditing to be carried out with a dedicated team to oversee this. It is more than likely that this team would be provided by the central laboratory service. In order to ensure that the devices remain compliant with regulations it is necessary that there is appropriate (increased) aftercare support provided by the central laboratory service. Currently, it seems that once implementation and initial training is carried out these support levels can be low in many cases. It is possible that this is a consequence of the design of POCT systems. Manufacturers of such devices have recognised that the main consumers/users of POCT in the future will be health professionals from a non-laboratory background and hence made significant effort to incorporate adequate internal quality controls within the devices so that the expertise of a trained laboratory professional is not required for routine operation and utilisation. Therefore, the newly incorporated internal quality control checks have displaced the requirement for some traditional control methods somewhat and in doing so potentially reduced the obligation for laboratory intervention (Gill, Shephard 2010).

The dynamic between those groups, firstly utilising the POCT devices in the clinic and, secondly, the central laboratory service that are responsible for test quality, has been found to be a fundamental consideration with respect to determining the reality of barriers to uptake of POCT. Central to this notion is the perceived reluctance to allow control of diagnostic testing beyond

the tight laboratory confines. Clinical opinion on this controversial area is seen to be significantly varied according to the results of this study. By separating responses into different clinical specialties some interesting findings can be appreciated. On the 10-point scale used (where 10 is strongly agree), emergency medicine clinicians (n=15) averaged a response of 6.7, anaesthetics and intensive care clinicians (n=5) averaged a response of 9.2, while those from within the clinical biosciences discipline (n=7) averaged a response of just 4. Perhaps unsurprisingly, those clinicians who are less directly associated with the central laboratory are in more agreement with this statement than those with closer associations. The majority of comments from respondents within the clinical biosciences environment were based around an opinion that, although the use of POCT displaced tests away from the central laboratory and hence reduced workload somewhat, this increased the risk of quality assurance errors being made by non-laboratory clinicians who were perceived as not being competent to perform such diagnostic tests. Some clinicians working outside of the central laboratory did comment that this reluctance to release the control of testing was understandable as diagnostic testing was the governance role of the service. However, a substantial number were in agreement that this issue significantly impacts upon the more widespread adoption of POCT within their clinical workplace. Again, it must be considered that improved training processes, along with increased aftercare support from the central laboratory, would do much to overcome the notion of clinician incompetence held by the clinical biosciences cohort. There is some recognition of the fact that this barrier is actually a necessary one, due to the potential dangers associated with quality errors in terms of patient care and wellbeing. Quality assurance becomes more complex as diagnostic testing becomes more decentralised, with a greater number of individuals having access to the devices. Despite controls implemented by manufacturers, POCT instruments are still greatly dependent on the expertise of the operator. As such, institutional principles of a quality management system must be rigorously adhered to by the operators of POCT devices, all of whom should be trained appropriately before they are permitted to operate the devices (Larsson, Greig-Pylypczuk et al. 2015). Comments made by all of the clinicians surveyed within this study indicate that they are unanimously of the opinion that POCT, and any other type of clinical technology for that matter, must be implemented and adopted into healthcare institutions in a controlled manner.

There were indications from the literature study that the implementation of POCT significantly increases the workload of clinical staff, hence acting as an impediment to its uptake and causing levels of dissatisfaction amongst these staff (Zydron, Woodworth et al. 2011, Fermann, Suyama 2002, Giuliano, Grant 2002). However, although there were variations in the results, the majority of respondents in this study indicated that this was not the case in reality. In fact, most comments made by clinicians specified that performing a test using POCT took either the same

or less time than sending a sample to the central laboratory and then “chasing up” the result. An analysis of the demographics of responses indicates that the clinical biosciences cohort are more of the opinion that POCT increases the workload of front line clinical staff in comparison to that of staff of the other disciplines in that, on the 10-point scale used to answer this question (where 1 was strongly disagree and 10 was strongly agree), general medicine clinicians (n=7) averaged a response of 3.4, while the clinical biosciences participants (n=7) averaged a response of 6.9. Clinicians working less closely with the central laboratory service tended to disagree more with the idea that this issue exists due to their belief that using POCT approximately equates to or is less than the time required to take a sample, send it to the lab and wait for a result. Conversely, professionals with closer links to the central laboratory argue that POCT increases the workload for their staff as in many cases they are responsible for ensuring the quality assurance of the devices via appropriate checks (quality control, calibration etc.). It must be considered however that increased workload does not solely encompass the performing of tests and QA procedures, but also includes an increased amount of training that operators must undergo in order to satisfy regulatory requirements (Rooney, Schilling 2014). With this in mind, it is difficult to argue that POCT does not add a burden of time to an already busy role of the typical clinical user.

The consistent disconnect in opinion between the central laboratory and mainstream clinical groups raises questions regarding whether the role of the central laboratory (and also relevant clinical care pathways) have adapted sufficiently to incorporate the efficient use of a POCT system. In this regard, the results from this study are inconclusive, in that a significant variation in opinion was obtained. Typically, patient pathways and the role of the central laboratory have adapted in areas where POCT has been embedded over a longer period of time, such as in diabetes management and warfarin control. Glucose testing is the largest sector of the professional POCT market, i.e. that performed by healthcare professionals and not by patients using “over the counter” devices (St John, Price 2014). The development of patient pathways and role of the central laboratory in the area of diabetes management, for example, is due to the trust that has built up over time with respect to the quality management of devices and the high reliability of results. Therefore, similar levels of trust are clearly required in other areas to allow the health service to adapt fully. This can be attained through the provision of clear evidence of performance and reliability of such tests. By assessment of the current rates of growth within the professional POCT market, infectious diseases is the most rapidly growing sector (St John, Price 2014) and as such may become more embedded within delivery of secondary healthcare in the near future.

The final category of barrier to adoption of POCT that was identified by the literature review study focused on device performance and data management. Interestingly, usability and analytical performance of POCT devices were found not to be major issues for the clinicians that took part in this primary study. These particular issues may have been a problem historically, but it would seem that with the development of new technologies and evolution of devices this is no longer the case. Developments in both paper-based and "lab on chip"-based microfluidic POCT devices have significantly expanded the range and complexity of these types of tests available and their associated analytical capabilities. Key developments in this regard include miniaturised, automated technologies and the development of long-term reagent storage strategies (Vashist, Luppa et al. 2015).

Connectivity and data management capabilities of POCT devices, however, were generally rated as being "poor" or "very poor" by participants in this study. Nevertheless, the majority of the respondents who indicated this also were of the opinion that the poor connectivity or data management did not make it more difficult to attain a timely and reliable diagnosis. The general consensus here was that POCT is used to obtain real time results that aid quick decisions, often in situations where access to previously recorded data is not important for direct patient care. Therefore, it would seem that, although the connectivity and data management capabilities of POCT are poor in comparison to that for CLT instruments, this does not act as an impediment to their intended utility overall. Nonetheless, better connectivity of the results from POCT devices to central healthcare systems was a common consideration for clinicians with respect to potential solutions to overcoming barriers to their uptake. It was apparent that the core issue here lies with the sheer number of different interfaces with which the different types of POCT device needed to be compatible. Whereas, CLT instrumentation generally all runs under one common interface, POCT devices are very fragmented in this respect thereby causing data management issues. The creation of a standardised interface for POCT would be a fairly simple and inexpensive solution to overcoming this problem.

The general utility of POCT was evaluated as part of this study in order attain as complete an assessment of the barriers to its adoption as possible. With respect to the potential benefits, the information gathered here categorically indicates that a rapid TAT and hence quicker clinical decisions/interventions are the most important advantages that POCT has in comparison to CLT. It is not unexpected that those who have used or have knowledge of the utility of POCT in their area of clinical specialty, will see this as the most obvious benefit. Other common advantages offered by POCT include increased efficiency with respect to patient management and improved satisfaction and convenience for both operator and patient. Unsurprisingly, the most indicated diseases/conditions deemed to benefit most from the use of POCT were the 3 areas where these

technologies have become most widely accepted and embedded, specifically blood glucose monitoring for diabetic patients, INR monitoring for patients receiving warfarin therapy and respiratory conditions.

By comparison, the 2 most common disadvantages of POCT in comparison to CLT were increased cost and quality issues stemming from untrained or non-competent staff using the devices. The reason that there is no definite "stand out" disadvantage indicated here is likely due to the fact that issues with POCT are highly dependent on the environment in which they are utilised. Whereas, the nature of technology will generally lend itself to improving TAT no matter where it is deployed, disadvantages such as quality issues are related to a number of factors such as how often the device is used in a certain department, the level of training and re-training that is carried out by the clinical institution and the turnover/rotation of staff within a department. What we can deduct from variation of response in this study is that opinion on the value of POCT is highly dependent on a range of factors including how the devices are utilised within a specific clinical environment and the associated support for their role.

4.5 NHS Validation

In order to validate the results from the 5 HSCNI Trusts as representing a true reflection of the wider UK health system as a whole, the electronic component of the study was hence replicated at NHS Frimley Health Foundation Trust. In total, 7 clinicians from this Trust took part, 5 from an emergency medicine background and 2 from a clinical haematology background. In terms of the economic considerations, the results were in line with what was indicated by the main study, namely that the majority of clinicians agreed that the cost of POCT was higher than CLT, yet also indicated that the use of POCT was cost-effective and that longer-term economic benefits were available through its use. In regard to quality issues, the results also followed trends seen in the main NI study, in that opinion was varied and a certain disconnect was identified between those utilising POCT and those responsible for POCT. Polarised opinion between clinical cohorts was noted with respect to; quality issues caused by the dispersion of devices leading to use by untrained or non-competent staff, over-complexity of analytical testing accreditation regulations for POCT and, levels of operator training and support for POCT provided by the central laboratory. One notable difference between this study and the main NI study was identified in the category of device performance and data management, specifically the connectivity of POCT. Whereas, those in the 5 NI Trusts generally rated connectivity as being poor, in the UK NHS study it was rated as being significantly high. This suggests that It is perhaps worth investigating if the systems and interfaces used in the NHS Trusts in comparison to HSCNI Trusts to see if the Northern Ireland system is lagging somewhat in this respect. However, this is beyond the scope of the current study. Considering the other issues in this category, both

analytical performance and usability were comparable in both parts of the study (NI and UK). The final category of staff and operational issues, like the main primary study conducted in NI, displayed much variation in opinion. However, it was difficult to identify any disconnect in opinion between clinical cohorts.

The study described here has been executed as a means of achieving the fourth research objective as defined in Chapter 1; to determine the relationship between those issues identified from a consideration of the academic literature (in Chapter 3) and the opinions of clinicians within the UK healthcare environment on the same issues. The findings of the academic literature have been used to frame this study that has successfully attained primary data used to determine such a relationship. Furthermore, the study has been used to help achieve the final 4 objectives as defined earlier in Chapter 1, namely; to identify the key advantages and potential benefits of POCT use within secondary healthcare; to identify the major disadvantages deemed to result from the use of POCT; to determine the clinical areas/situations in which POCT can provide the most benefit in secondary care, and; to suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption? Data on the advantages/benefits, disadvantages, areas of potential best practice and recommendations for overcoming barriers has been collated and will be used along with such information gathered from the following 2 primary studies in order to fully achieve these objectives.

Notwithstanding the minor variations noted above, it can be deducted that the results of the main NI centric study are indeed representative of the wider UK health system as a whole. However, it is acknowledged that the UK system is not homogeneous with respect to utility and experience of POCT. Moreover, it does not reflect that of POCT as a global entity. Hence, it is deemed important to gain clinical opinion from within a health system significantly different in nature to the UK system of free healthcare provision, where the management of care is determined by specified clinical pathways based on resolution of the episode and quality of care, rather than on supplementary factors such as the level and substance of an individual's insurance policy, as in the US system of healthcare. To this end, research was conducted in the US healthcare system and the results compared to findings in the UK as outlined in the next chapter.

4.6 Statistical Comment

In addition to that described here, a statistical analysis has been applied in order to further investigate the perceived differences in opinion observed between those responsible for POCT

(denoted here as clinical bioscientists) and the clinicians who are responsible for use and operation of the devices as diagnostic tools. Specifically, this study has indicated 3 areas where such differences in opinion exist. Firstly, that the decentralised nature of POCT gives rise to opportunities for untrained / non-competent staff to use the devices, hence leading to certain quality assurance issues (Q10). Clinical bioscientists were found to have a very polarised and strong opinion that this was the case. By analysing the data by way of the Chi-square test through a comparison of responses by clinical bioscientists versus clinicians, a p-value of 0.011 was returned. Being under the threshold value (<0.05) it can hence be deducted that the differences of response between these 2 clinical groups are indeed statistically significant and are not down to chance.

The second area where clinical groups appeared to offer differing responses was with respect to whether the utilisation of POCT significantly increased the workload of front-line clinical staff, where clinical bioscientists were of a stronger opinion that this was the case. Again, by application of the Chi-square test, a p-value of 0.039 was returned. Once more, this has determined this difference in opinion as being statistically significant.

The third identified area where differences in opinion were observed between the clinical groups was with respect to the reluctance to allow the control of diagnostic testing to move outside of the confines of the clinical laboratory (Q19). As was to be expected, clinical bioscientists were found to be less in agreement with this statement in comparison to clinicians. Following the same process of analysis as before, a p-value of 0.306 was found in this case. Being above the threshold value, this suggests that the difference in opinion found here may be down to chance and cannot be deemed as being a statistically significant difference.

Chapter 5

Clinical Perspectives on Barriers to Adoption of POCT from within the US Healthcare System

5.1 Study Objective

The research described herein follows on logically from the findings of the core study presented within Chapter 4, which focused on the barriers (real and/or perceived) to the uptake and utilisation of Point-of-Care Testing (POCT) devices within the UK National Health Service (NHS), i.e. in circumstances where provision of care that is free of charge at the point of delivery. In a global sense, it is recognised that such UK-centric findings do not truly reflect the healthcare sector as a whole and that a comparison with a system that has a more direct charging model is warranted. Accordingly, the research reported here utilises a representative sample of the US health system, where economics and levels of the patient's health insurance play a more influential role with respect to the treatment provided for resolution of the medical episode (Shi, Singh 2015, Feldstein 2012). The significance of the role that economic factors can play in the adoption of POCT devices is already apparent from research carried out to this point and so focusing on a setting where economics plays an enhanced role in service delivery has the potential to yield findings of much interest. As such, the key research objective here is to determine if there is a significant difference in the perspectives to POCT uptake between the 2 healthcare service models and specifically if the underlying economic model of the relevant health system has an influence on clinical opinion regarding the usefulness and utilisation of POCT devices within the hospital environment.

5.2 Study Development & Design

In order to ensure that the comparison provided a fair account of any significant differences between UK and US clinical practice, the overall study design for the latter was, as far as possible, a duplicate of that employed for the former. Any differences reflect the need to make some appropriate changes to facilitate the intended study group. Furthermore, emphasis was placed upon attaining insight into why there may be differences of opinion based on the model of healthcare delivery. In particular, it was deemed important to implement the face-to-face aspect of the study in order to attain detailed opinions on the potential advantages, disadvantages and overall clinical utility of POCT from senior consultant-level clinicians and to this end field work was undertaken.

Utilising existing Ulster University connections, the University of Massachusetts (UMass) was selected as the collaborating organisation and suitable clinicians within the UMass Memorial Hospital (clinical partner of the UMass Medical School) in Worcester, MA were identified and invited to take part in the study through face-to-face interviews to be conducted on site at the hospital. This group of clinicians was therefore selected as a representative sample of the US health system for the purposes of the proposed comparison. With the assistance of a local collaborator at UMass Memorial Hospital, it was possible to recruit a sufficient number of clinicians to participate in the face-to-face interviews rather than use an on-line version of the (slightly modified) questionnaire.

Careful consideration was given to how to best adapt the study configuration to account for the nature of the US healthcare system whilst maintaining an appropriate frame of reference to allow comparison of the outcomes with those from the UK study. In order to achieve this important end, it was decided that the questions should be identical to those in the UK study with 1 additional question, this being *"Are you aware of any differences between the US and UK healthcare systems that could affect the uptake of POCT within the clinical environment?"* In this way, any fundamental differences in the respective health systems that could influence and/or affect uptake and utilisation of POCT devices should be evident.

Existing research governance and ethical approvals used for the UK study were submitted to the relevant office at the UMass Memorial Hospital and approvals granted to enable the interaction with clinicians to be undertaken.

5.3 Study Results

A total of 21 face-to-face interviews were carried out with senior clinicians on the site of the UMass Memorial Hospital, Worcester, MA. A range of clinical specialties were targeted for these interviews in order to provide as diverse a background as possible with respect to the POCT experience of the study participants. Table 5.1 provides a breakdown of respondents in terms of their clinical specialty. The most represented categories were clinical biosciences, general medicine and POCT experts with 4 participants each. The POCT experts, all of whom were identified as having substantial knowledge on the area were advanced nurse practitioners in this case, who play a significant clinical role within the US healthcare system with respect to the utilisation of POCT.

Table 5.1 - Breakdown of study participants with respect to clinical speciality (n = 21).

Clinical Specialty	Number of Respondents
Emergency Medicine	1
Clinical Biosciences	4
General Medicine	3
Orthopaedics	2
Paediatrics	2
Dermatology	1
Cardiology	3
Psychiatry	1
POCT Experts[1]	4

[1]*Four advanced nurse practitioners in emergency medicine, cardiology, immunology and general specialisms were identified as having expert knowledge on the area and were subsequently invited to participate in the study.*

Of the total (21) participants, 19 indicated that POCT devices were used in their area of clinical practice. The 2 respondents who did not indicate this to be so, were involved in paediatric neurology and psychiatry. However, they did have substantial knowledge on the clinical utility of POCT devices and so were deemed to be valuable to the study. Those respondents that were currently utilising POCT in their area of clinical practice were asked to give an estimation of how many such tests were performed as a percentage of all of the diagnostic tests performed in their respective areas, with the average figure returned being 21%. This is a very similar result to findings of the UK study where the value was 20% (based on 44 responses).

To further gauge the background and skills of the participant group, clinicians were questioned with respect to the nature of their particular expertise in the practical use of POCT devices, with the data presented in Figure 5.1. Proficiency with actual POCT devices was significantly varied in this group, with the most popular response being “untrained in the use of POCT devices” (7 of 21 respondents). However, 6 of 21 respondents stated that they were “highly proficient” and were in fact recognised trainers of the use of POCT, while 5 participants rated themselves as having “basic level capability” in the unsupervised use of these devices.

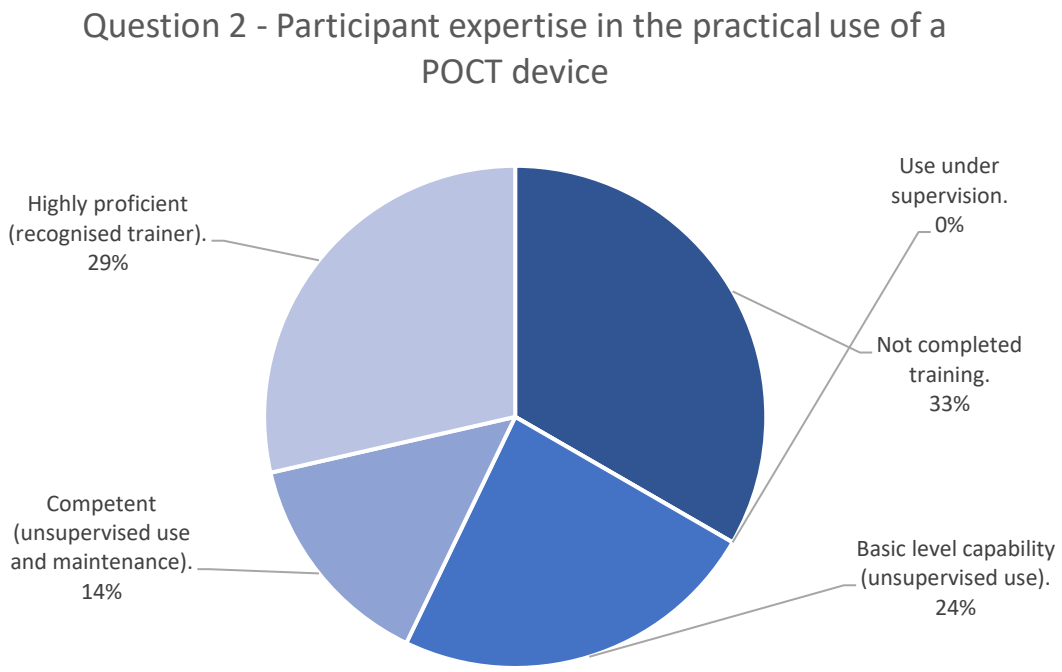

Figure 5.1 - Areas of clinical expertise as a function of POCT use by study participants (n=21).

Figure 5.2 outlines the most common types of POCT utilised within the respective clinical care area of the respondents. Various types of blood test available through the use of POCT were of most prevalence with blood gas and blood glucose tests along with urinalysis and urine pregnancy tests all featuring highly. Within this study, only blood glucose POCT assays were used by over half of respondents (53%). In comparison, 4 tests were used by over half of participants in the UK study (blood gas, blood glucose, urine pregnancy and blood lactate), with blood gas and blood glucose being very prevalent, used by 85% and 79% of clinicians respectively. In general, it would seem that the more specialised the clinical background of the respondent, the more specific (and specialised) the type of test used. For example, the Dermatology specialist participating in this study indicated that they used POCT for analysis of skin samples and it is unlikely that this particular test would be used in any other area of practice on a routine basis.

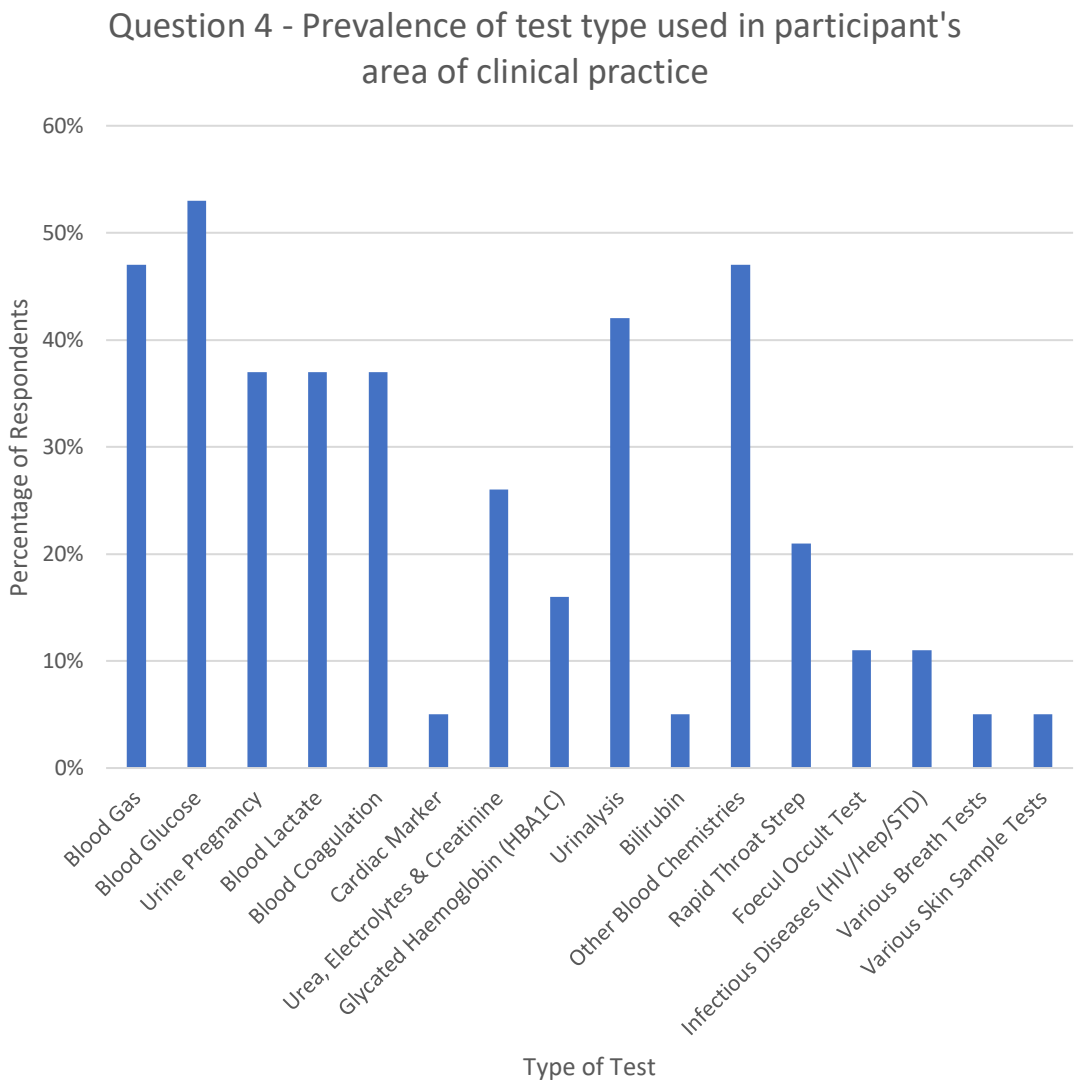

Figure 5.2 - Most common POCT devices used in various areas of clinical practice with respect to percentage of respondents for each (n=19).

5.3.1 Economic Issues

The US clinical participants were questioned on the issues surrounding the economics of diagnostic testing within the hospital environment. Answers were significantly varied in terms of the actual cost per test of POCT in comparison to that undertaken utilising Central Laboratory Testing (CLT), as outlined in Figure 5.3. Just 7 of 21 participants agreed that the cost of POCT was higher than CLT (33%), while 9 (43%) thought the opposite. The remaining 5 participants were not sure and opted not to give a response to this question.

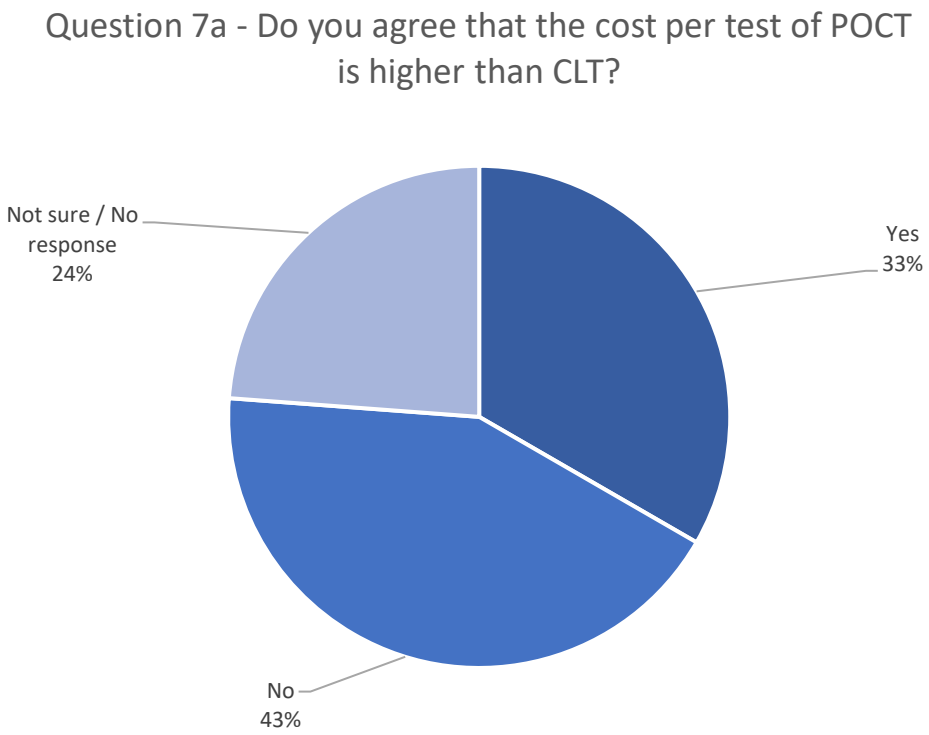

Figure 5.3 - Clinician indication of POCT cost per test in comparison to that for CLT (n=21).

Notable comments from those participants who agree that POCT has a higher cost per test than CLT include:

- *"Cost borne by the patient is often higher, and cost to the clinic is higher in order to meet training and regulatory requirements."*
- *"Universally central laboratory testing is cheaper, however POCT brings in more income for the clinic."*

By contrast, some comments made by respondents who disagreed with this statement include:

- *"The increased efficiency of POCT must be considered."*
- *"Budget reimburses a minimal amount for POCT."*
- *"The hospital has privatised the laboratory off-site".*

Participants were also asked to give their considered opinion on the statement that POCT provides longer term economic benefits, for example reduced hospital stay, reduced outpatient appointments etc. As previously, the responses were given on a 10-point scale with the resulting data summarised in Figure 5.4. Over half of the responses (57%) either "agreed" or "strongly agreed" that POCT provided these longer term economic benefits, thereby representing the majority of the response group. However, a significant proportion of respondents remained "neutral" (24%) in this respect, while 19% of respondents either "disagreed" or "strongly disagreed" with the statement.

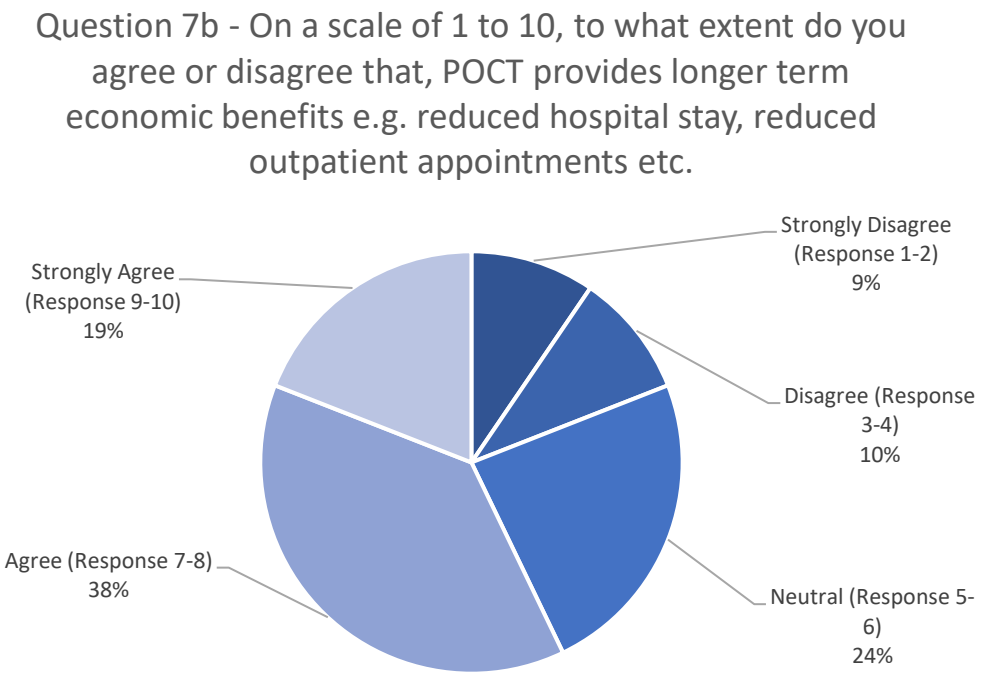

Figure 5.4 - Clinician opinion on the longer term economic benefits attainable through the use of POCT (n=21).

One comment made here by a participating orthopaedic consultant (who gave a "neutral" response) was of particular interest:

- *"This depends entirely on the setting. For an anaesthetist, yes this would be the case. However, in my case I don't want the result immediately, this would waste time and slow things down. Sending the test to the laboratory and sending the patient home improves patient flow. The patient will usually return in a week's time for an outpatient appointment anyway so we can discuss the result then. Therefore, POCT in my opinion has limited long term benefits and using the central laboratory actually improves patient management."*

Those who "disagreed" or "strongly disagreed" with this statement were questioned further as to why they thought that potential economic benefits are not being realised through the use of POCT. Responses were as follows:

- *"Length of stay and further tests are driven by the data, the method of test is not significant."*
- *"Benefits are not being realised because there is a poor relationship between the hospital and the laboratory. There are tremendous bureaucratic hurdles."*

- *"I don't think longer term economic benefits are available through the use of POCT. It is only useful for critically ill patients. If the test is not required within 5 minutes then the sample should be sent to the laboratory."*
- *"POCT is more expensive and provides testing on a reduced number of analytes, I don't believe economic benefits are available."*

Generally, participant opinion was that the utilisation of a POCT system was cost-effective. As shown in Figure 5.5, 18 of 21 clinicians indicated that this was the case. Interestingly, no respondents indicated that they disagreed with this statement, while 3 were not sure and opted not to give a response. One participant added:

- *"POCT is cost-effective, not cost-saving. In my opinion it makes good use of the extra expense incurred."*

Comments also were made here with respect to the importance of test accuracy. Clinicians were of the opinion that POCT provides a cost-effective system as long as the accuracy of the testing concerned is good enough to enable a clinical judgement to be made and, in particular, additional tests are not having to be carried out subsequently by CLT thereby causing duplication of tests and associated increase in costs.

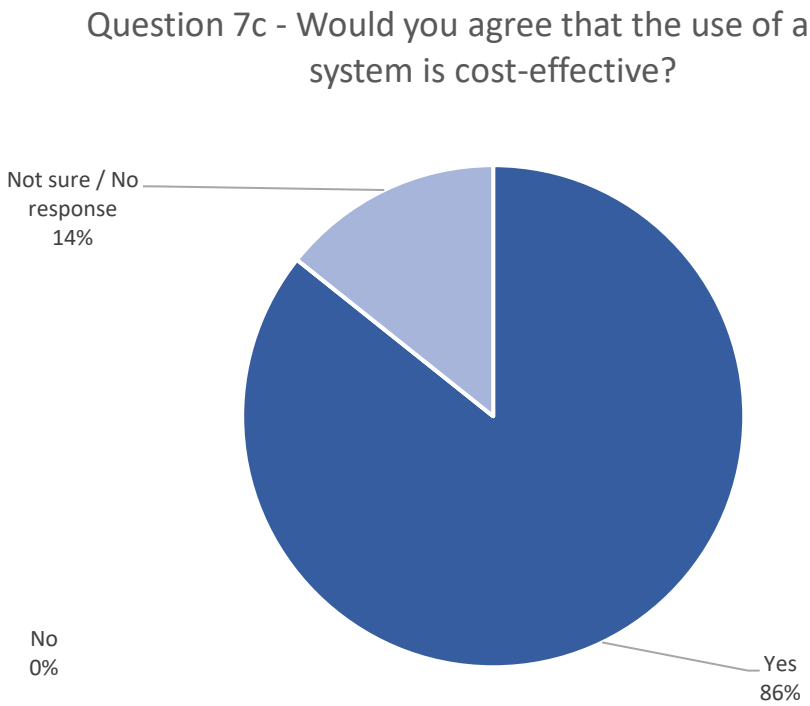

Figure 5.5 - Clinician opinion of the cost-effectiveness of a POCT system (n=21).

Significant variation in the responses made to questions on procurement, reimbursement and budgeting with respect to POCT and the intrinsic interdepartmental nature of such were

received, as summarised in Figure 5.6. Some 33% of respondents either "disagreed" or "strongly disagreed" that the interdepartmental nature of POCT was sufficiently accommodated for within their area of clinical practice, while 33% of responses were "neutral", and 34% of responses "agreed" or "strongly agreed" that these factors were sufficiently accommodated for in their experience. Although there were some indications in the comments received that the significant majority of POCT devices within the US hospital concerned were not utilised on an interdepartmental basis (and hence the question was not entirely relevant to their situation), there were some other interesting comments with respect to the economic nature of the US health system, including:

- *"The hospital wants to make money and the laboratory is more expensive to the patient than POCT and so budgeting and reimbursement do not accommodate POCT very well."*
- *"The laboratory has been outsourced to a private company. The hospital gives a budget to the department for diagnostic tests that POCT comes out of."*
- *"The majority of POCT use is in inpatient situations where we are moving towards DRG (Diagnostic Related Group) costing where the hospital is paid for the incident rather on how many tests are carried out, as was done previously."*

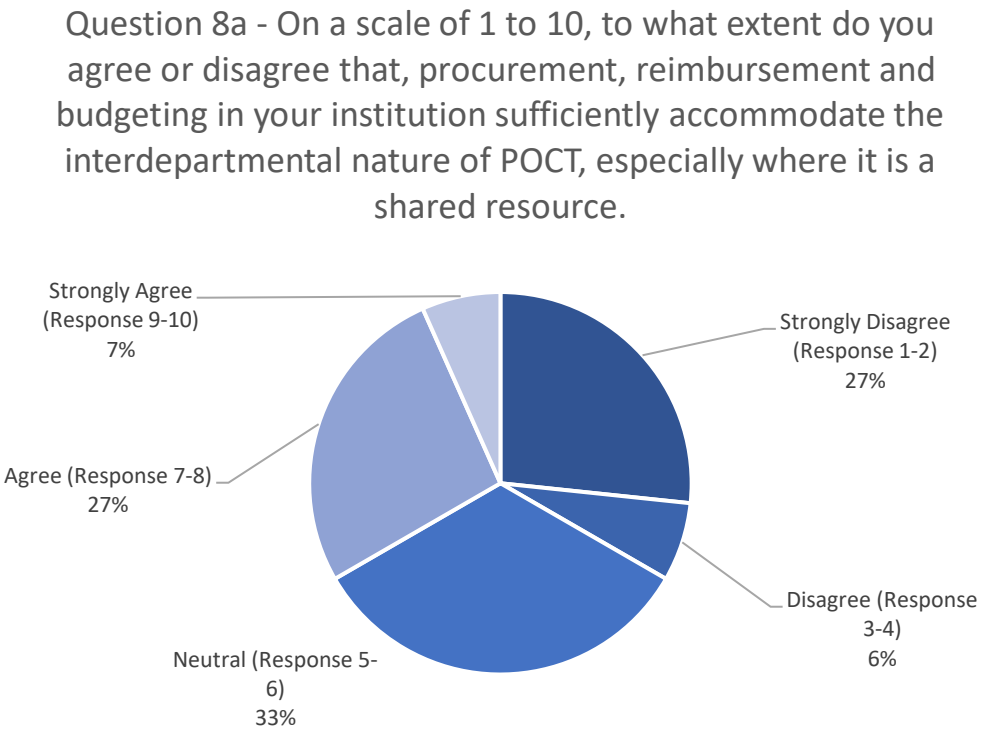

Figure 5.6 - Clinician opinion on procurement, reimbursement and budgeting for POCT with respect to the interdepartmental availability of such devices (n=15).

Importantly, all of those respondents who "disagreed" or "strongly disagreed" with the premise that the interdepartmental nature of POCT was sufficiently accommodated indicated that it was difficult to utilise POCT to its full potential as a result.

As was the case for the UK study, the US sector participants were questioned on the relevance of certain economic related issues that were identified from the systematic literature review. These issues include; difficulties in justifying the use of POCT due to the higher cost per test in comparison to traditional testing methods; difficulties in justifying the implementation of a POCT system due to unclear cost-effectiveness and complexities in comparing to traditional methods of testing; difficulties in justifying the implementation of a POCT system due to high initial outlay costs; issues with regards to budget contributions due to the "silo" nature of separate departmental budgeting, and; difficulties in obtaining reimbursement for POCT. The responses are summarised in Figure 5.7 and reveal that the dominant response for all 5 issues is that of "not relevant", but that otherwise the level of response varies somewhat across the issues. In terms of the higher cost per test of POCT acting as a barrier to utilisation, clinicians generally indicated that clinical gains were most important and that the required immediacy of test result took precedence over cost. As a result, 13 of the 20 responses received here (1 clinician chose not to give a response here due to lack of knowledge) indicated that this issue was either "not relevant" or "rarely relevant" within their area of work. However, there was also an observation made by a participant that if a rapid result was not important then POCT should not be used because of the increased cost and also because laboratory tests were trusted more by clinicians. There was much more variation seen with respect to opinion on difficulties gauging the true cost-effectiveness and making economic comparisons with traditional diagnostic testing methods. Only 6 of 20 respondents here indicated this was "not a relevant" issue to them, while a further 6 respondents indicated that this issue was either "fairly relevant" or "very relevant" within their institution. The strongest trends here were seen with respect to budget contributions towards POCT due to "silo budgeting" and difficulties in obtaining reimbursement for POCT, wherein 9 and 12 participants, respectively, indicated that these issues were "not relevant" to them. An important consideration with respect to reimbursement was raised by comments made by a participant that indicated that reimbursement is not an issue as long as you use the particular test/device recommended by the insurer. In this regard, the participant indicated that insurance cover that the patient has determines what brand of test can be utilised by the clinician. This is similar to the situation with insurance cover and drugs, where certain tiers of cover may insure for branded drugs, while others will only insure cheaper generic alternatives. If the recommended test is not available and another is used instead, then reimbursement may not be made by the insurer. This is clearly a major difference between the US and UK healthcare systems. When the issue of high initial implementation costs for POCT was considered, only 3 responses indicated this issue is "fairly relevant" or "very relevant" indicating that this is not a significant issue in terms of impeding the update of POCT uptake in the US healthcare system.

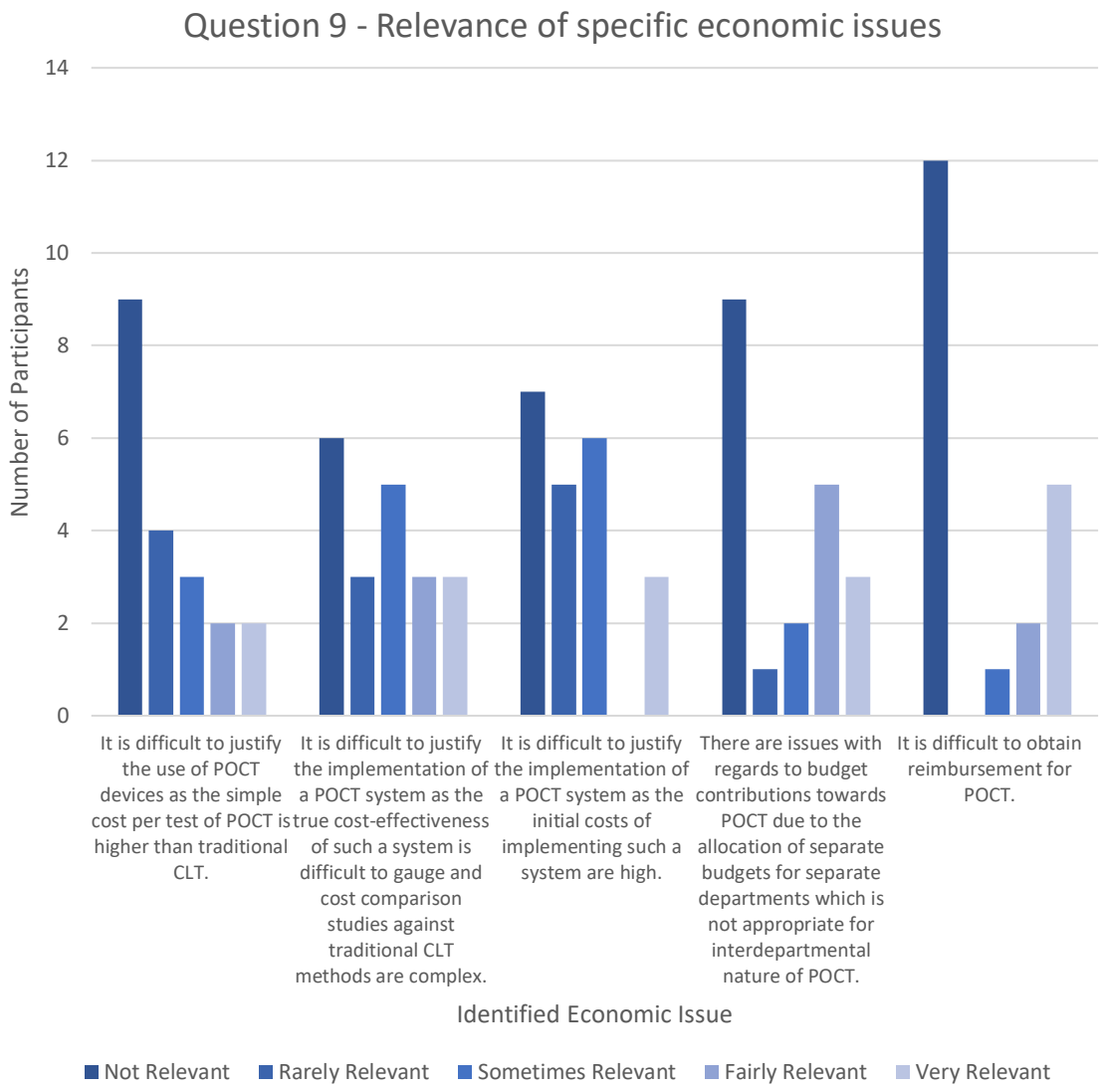

Figure 5.7 - Clinician opinion on relevance of specific economic issues associated with POCT within their areas of clinical practice (n=21).

5.3.2 Quality Assurance & Regulatory Issues

Whilst quality assurance issues may be similar across various healthcare systems (both free at the point of delivery and insurance based), there is potential for national/regional regulatory requirements to have a significant effect upon how POCT may be utilised. The US clinicians were questioned on whether the dispersed nature of POCT devices contributed to their use, or potential misuse, by untrained or non-competent users, with the results summarised in Figure 5.8. Interestingly, opinion was quite polarised with respect to this perceived barrier to POCT adoption, in that while 50% of respondents either “agreed” or “strongly agreed” that this was indeed an issue, 45% of participants also either “disagreed” or “strongly disagreed”.

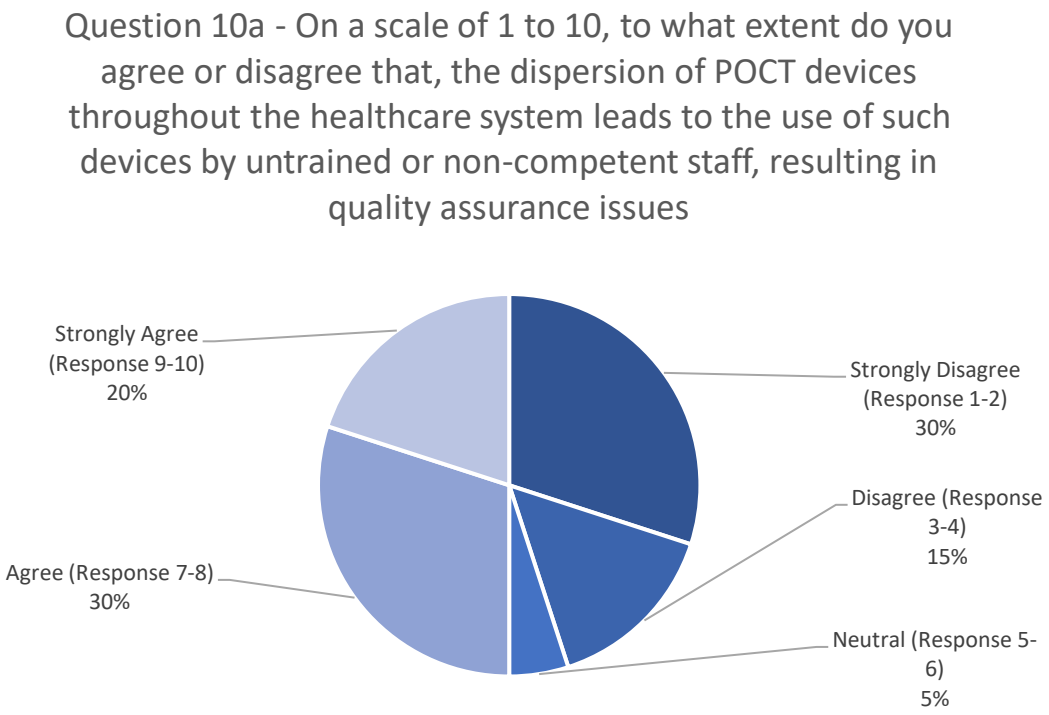

Figure 5.8 - Clinician opinion on how the dispersed nature of POCT devices can lead to their use by untrained or non-competent staff, resulting in quality assurance issues (n=20).

Some of the interesting comments from those who were in agreement with the proposition include:

- *"Devices are common in outpatient areas and a wide range of staff have access."*
- *"CLIA (Clinical Laboratory Improvement Amendments of 1988) waived tests are a huge worry as people don't need much training to use them. Just because the tests are easy to use does not mean they are not complex in nature."*

Conversely, comments from those participants who were in disagreement with this being an issue include:

- *"It doesn't matter who uses the device, it's the info that comes out and the clinical judgement made on that. Anybody can use the device, that is not important."*
- *"The laboratory watch over everything carefully so it is not a problem."*
- *"We have refresher training every 6 months so that staff are always competent."*

It is interesting to note that of the participants who "agreed" or "strongly agreed" that an issue existed with untrained or non-competent staff potentially utilising the POCT devices (50% of total response), 3 (15% of total response) indicated that they believed this did not produce a difficulty in attaining a timely and reliable diagnosis in comparison to traditional CLT. The reason for this was their belief that POCT devices should be fool-proof with no opportunity for error,

and that anything that required complex steps in the operation of such a test should not be available as a POCT device.

When questioned about the complexity of the current accreditation for analytical testing based on POCT, a number of participants were unsure of the regulations involved. As a result, 3 participants did not give a response to this particular question. The overall spread of clinical opinion obtained here is indicated in Figure 5.9. Significant variation in response is seen here, with those in the "strongly agree" category being of the lowest number (6%). Opinion was then evenly split across the 4 other categories; "agree", "neutral", "disagree" and "strongly disagree". Comments from clinicians ranged from belief that there were not enough regulations in place, leading to big problems with quality assurance, to tests being promoted from (CLIA) waived to non-waived categories on the manufacturer's recommendation, meaning very few staff have the qualifications necessary to perform the test. An example of this that was cited was that if a manufacturer does not recommend its use for critically ill patients, what normally is a waived test (and requires basic qualifications to operate) becomes a non-waived test when utilised within the ICU (Intensive Care Unit) environment. Interestingly, 3 of the 5 clinicians who responded in the "agree" and "strongly agree" categories were of the belief that "overly complex" regulations did not affect the ability to attain a timely and reliable POCT diagnosis in comparison to CLT. Generally, these individuals were of the opinion that regulatory requirements were only a barrier to uptake of devices prior to implementation and that once the devices were fully deployed this no longer posed a problem to actual device use.

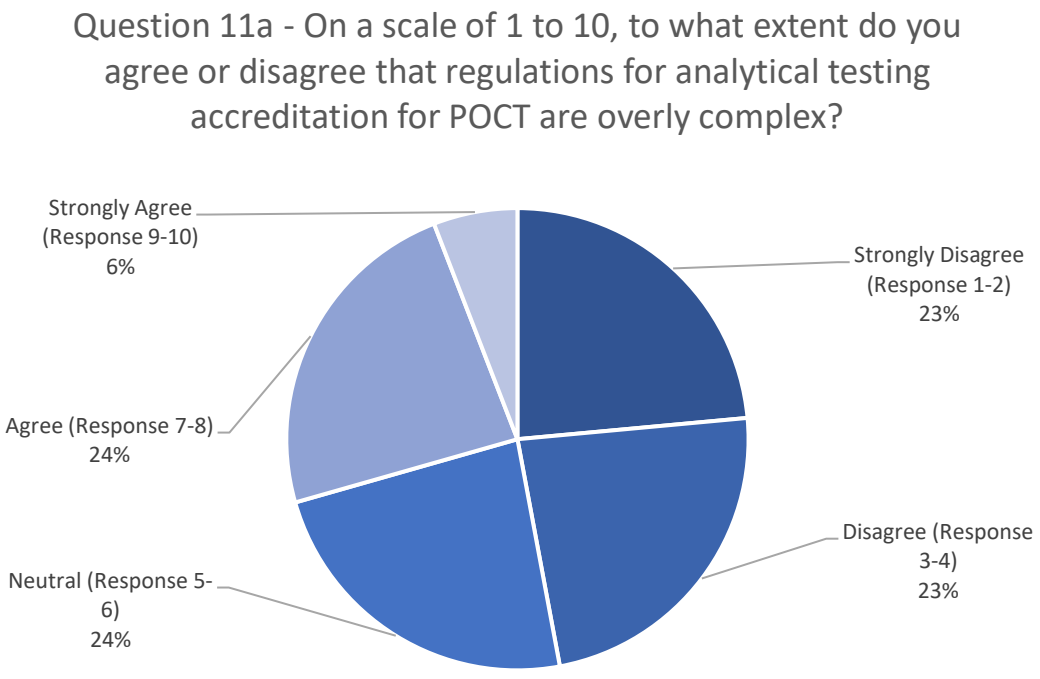

Figure 5.9 - Clinician opinion on the complexity of the regulatory requirements and accreditation for analytical testing using POCT devices (n=17).

Another important consideration with respect to the role of regulatory requirements is the appropriate training of staff to comply with such requirements. Levels of training can of course impact directly on the uptake and utilisation of POCT. In this study, participants were asked about the levels of training and support on regulatory compliance that was provided by the central laboratory in their place of work with the results shown in Figure 5.10. The responses were again varied with 4 participants not giving a reply to this question, which was again due to their lack of knowledge on the regulatory requirements in place. Some 44% of participants responded in the "very low" area of the 10-point scale, with 1 clinician suggesting that the reason for the lack of training and support provided was because the laboratory saw POCT as direct competition to their services and hence income, and so did not want to support it. Another responder indicated that, in general, it was clinical staff who trained other clinical staff and that the (central) laboratory did not reach out to help. However, 31% of participants also responded within the "high" category, and a further 19% indicated that a "very high" level of training and support was provided by the CLT service. These latter responders also indicated that the on-site laboratory looked after POCT and provided full oversight. It should again be noted that all of participants interviewed in this study were from the same US hospital and so this variance in opinion strongly suggests that there is no coherent strategy for POCT use.

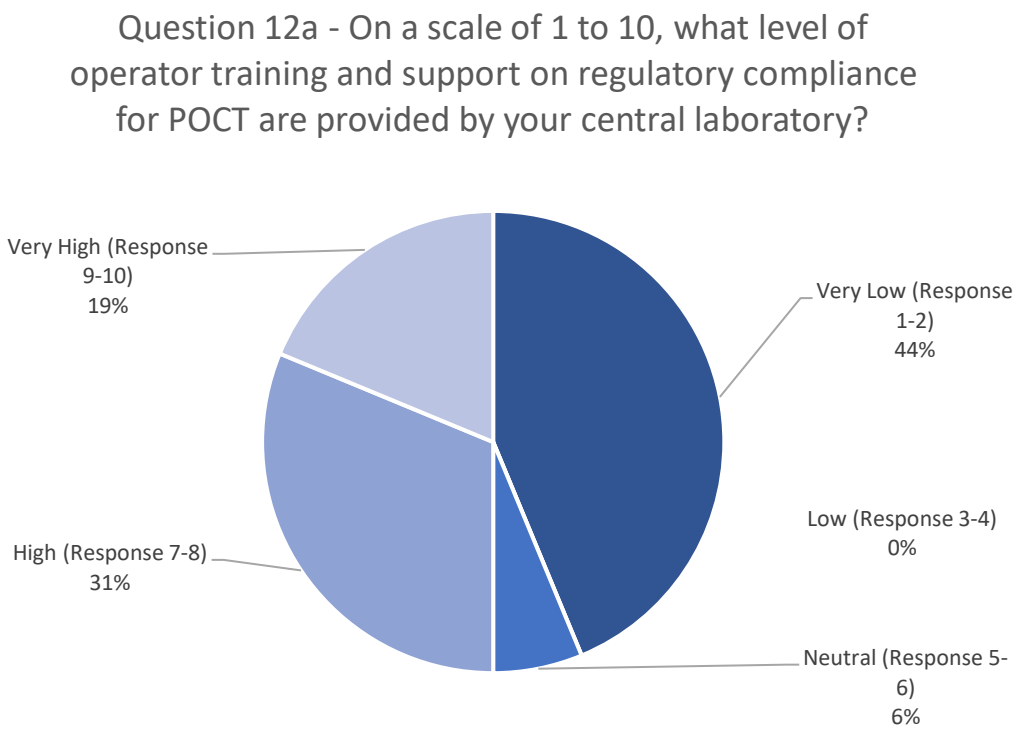

Figure 5.10 - Clinician opinion on the on the levels of regulatory compliance and operator training and support for POCT provided by their central laboratory service (n=16).

Of the 7 respondents who indicated a “very low” level of training and support provided, 5 believed that this subsequently made it more difficult to attain a timely and reliable diagnosis utilising POCT in comparison to CLT. The 2 participants who didn’t believe this to be the case were of the opinion that adequate training and support was attained without the involvement of the CLT and so this was therefore not seen as an issue.

For this category of barrier to adoption of POCT, the issues identified as prevalent within the previously reviewed literature were analysed in terms of their relevance to US clinicians and their respective clinical specialities with opinion on the relevance of these issues summarised in Figure 5.11. The issues of interest included; errors caused by incorrect quality assurance procedures by untrained/non-competent staff operating the POCT devices; issues for non-laboratory operators of devices due to regulations written for traditional laboratory equipment being blindly applied to POCT; issues with maintaining compliance due changes in the regulations associated with POCT; issues with maintaining regulatory compliance due to the dispersed nature of POCT, and; a lack of development of POCT devices caused by product approval hurdles discouraging economic investment in their development. In this case, 6 clinicians did not give a response for questions 13b, 13c and 13d due to their lack of knowledge on the regulatory requirements for POCT. Overall, the highest response category was “not relevant”, suggesting that these issues are not of high importance within the US clinical environment investigated here. Although over just half of the respondents here were of the opinion that quality assurance errors caused by untrained or non-competent staff operating devices was not a significant issue within their place of work, there was some uncertainty as to whether errors are not being routinely monitored and then only come to light if they are reported. Therefore, there is a distinct possibility that error rates are higher than those reported due to untrained or non-competent staff operating devices. Similarly, whilst 7 of the 14 (actual) responders were of the opinion that lack of regulatory compliance caused by the dispersed nature of POCT devices was not a relevant issue in their area of work, 1 clinician did specifically comment that, in their experience, glucometers were difficult to control in this respect, being used in 2 locations by approximately 3000 nursing staff and hence making them notoriously difficult to adhere to regulatory compliance. The strongest opinion offered by the respondents here was that 70% of participants indicated that product approval hurdles did not discourage economic investment in the development of POCT. In fact, comments attained here imply that in the US there are many drivers for POCT development, including the military, who have been a big supporter of POCT since the heightened threat of bioterrorism. In addition, the FDA (Food & Drug Administration) in the US are also very keen to develop new POCT technologies. The clinicians involved in this study were generally of the opinion that issues regarding

reimbursement for POCT was the main impediment to new device development and thereby the economic investment required.

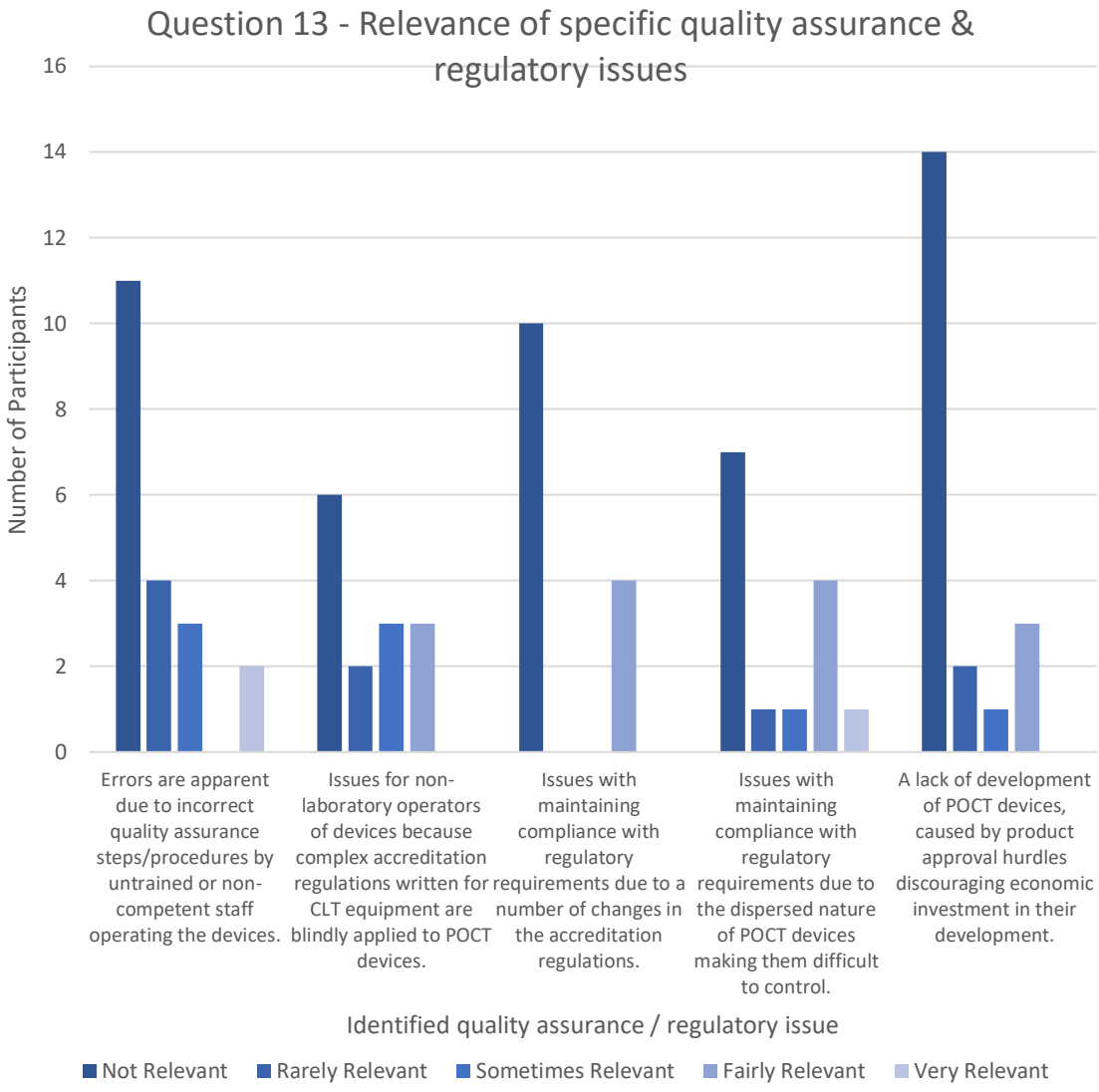

Figure 5.11 - Clinician opinion on the relevance of specific quality assurance and regulatory issues within their clinical institution (hospital) (n=20).

5.3.3 Device Performance & Data Management Issues

Device performance and data management issues were also assessed in this study. The first area of investigation focused on the perceived reduction in analytical performance of POCT devices in comparison to traditional CLT instruments, and how this can affect their uptake and/or utilisation. As can be seen in Figure 5.12, the US clinicians were generally of the opinion that the analytic performance of POCT devices was good, with 58% of responses rating them "high" and a further 21% rating them as "very high" (7-8 and 9-10 on the 10-point scale respectively). The remaining 21% of responses were of a "neutral" opinion (5-6 on the 10-point scale). Interestingly, no participants believed that the analytical performance of POCT devices was "poor" or "very poor" using this scaled method of response. The comments made by the

clinicians suggested a general thought that POCT devices were there to be used as a screening service rather than a fundamental diagnostic testing service, and hence their analytical capability was appropriate to perform this function. Specific comments included:

- *"By nature, POCT is not as accurate as the central laboratory, but POCT is used as a screening test and not as a diagnosis, and is fit for this purpose."*
- *"There are inherent limits to a POCT device but these are stated by the device. This is a compromise for the convenience of the test."*
- *"POCT is viewed as a screening exam so is not perfect."*
- *"Blood glucose testing provides a good example of the analytical quality of POCT. The result is clinically acceptable but not up to central laboratory standards. Problems arise when clinical staff are unaware of the limitations in comparison to traditional lab testing."*

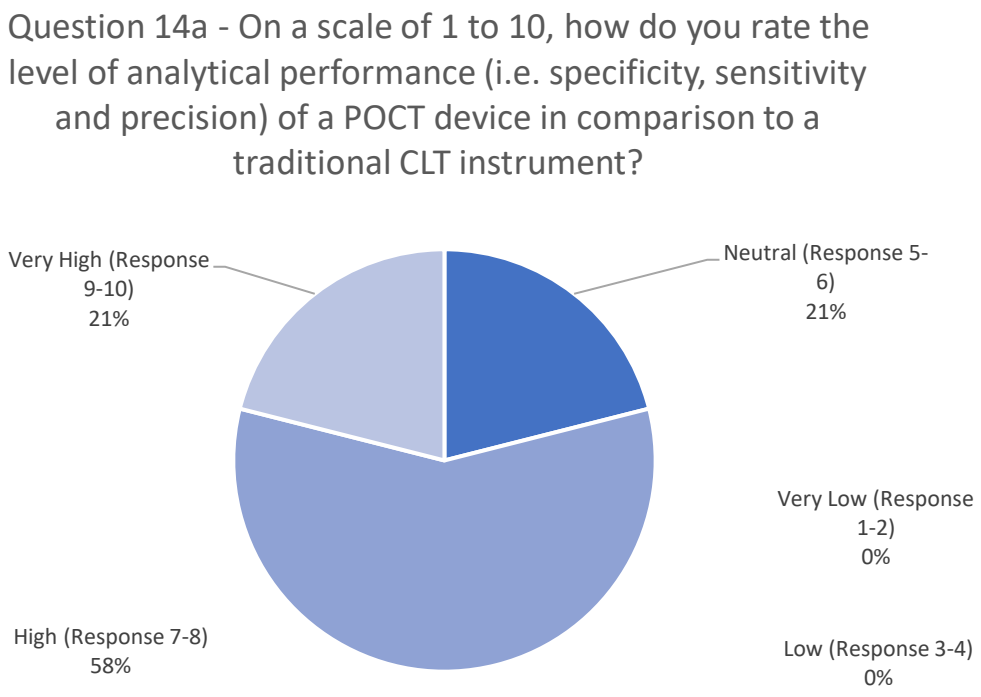

Figure 5.12 - Clinician opinion on the level of analytic performance offered by POCT devices (n=19).

As shown in Figure 5.13, when clinicians were asked about the connectivity of POCT devices to central healthcare and patient record systems, opinion was significantly varied. Based on the comments made by participants it was apparent that POCT connectivity varied from one department to another. Whereas, in some departments such as Immunology, results were simply written into records, in others such as the Emergency Room (Department) results were directly linked with electronic record systems. It would seem that the departments directly entering POCT results into record systems were worried that some detail could be missed due

to the lack of an automatic process. Clearly, the substantial variation in levels of data connectivity across the hospital led to the variance in opinion on this matter.

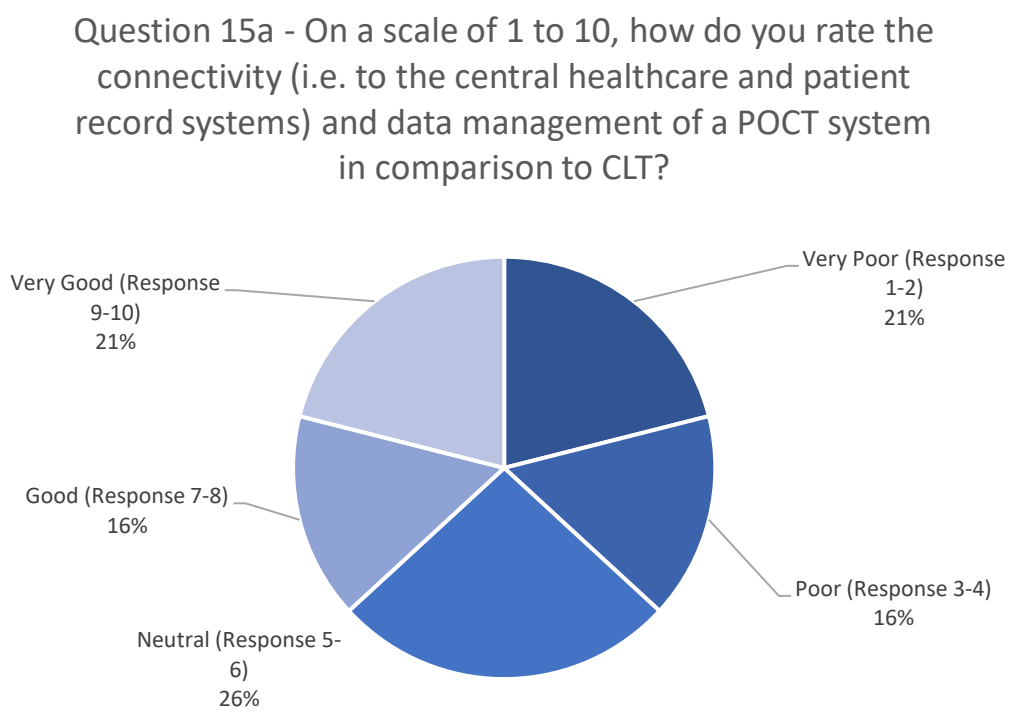

Figure 5.13 - Clinician opinion on the connectivity and data management capabilities of a POCT system (n=19).

The 7 respondents who indicated connectivity as being “poor” or “very poor” (using this scaled method of response) in comparison to CLT were asked if this poor connectivity made it more difficult to attain a timely and reliable diagnosis and all 7 denoted that this indeed was the case.

In terms of assessing the difficulty of performing tests using POCT, as illustrated in Figure 5.14, 76% of participants were of the opinion that POCT devices were “very easy” to use when compared to traditional instruments. A further 10% of respondents signified their operation as being “easy”, whilst the remaining 14% of study participants gave a “neutral” response. In this case, no respondents were of the opinion that the operation of POCT devices was either “difficult” or “very difficult”.

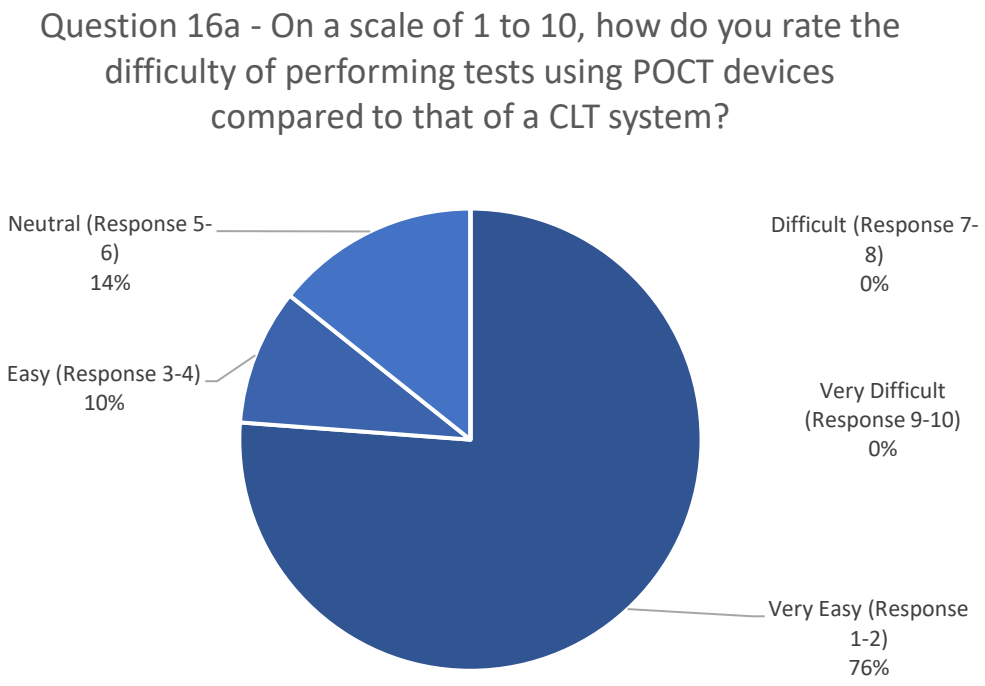

Figure 5.14 - Clinician opinion on the degree of difficulty associated with performing tests using POCT devices (n=21).

Opinion on the relevance of specific issues relating to device performance and data management that were identified in the relevant literature (Chapter 3) is outlined in Figure 5.15. The strongest opinion recorded was that 80% of respondents indicated that operators did not encounter significant difficulties with the use of POCT in their place of work. Furthermore, 40% of respondents indicated that a reduced analytical performance from POCT devices was "not relevant" to them within their specific workplace, while a further 25% of respondents replied that this particular issue was "rarely relevant" to them and 25% more were of the opinion that this was "sometimes relevant" to them. The remaining 2 responders thought that this specific issue was "fairly relevant" to them. Hence, it can be determined from this study that this issue is not of significant relevance within the US clinical institution concerned. The replies to the issue of connectivity and subsequent data management that might result from the reduced capabilities of POCT showed more variation. While 40% of respondents again signified a "not relevant" response, 35% indicated that this issue was "very relevant" to them, thereby giving a substantially polarised opinion. As noted in the responses to Question 15a, there was significant variance in opinion with respect to the connectivity levels of POCT devices in comparison to that associated with the more traditional CLT methods. It was apparent from these responses that the levels of connectivity varied greatly from one department and/or clinical area to another.

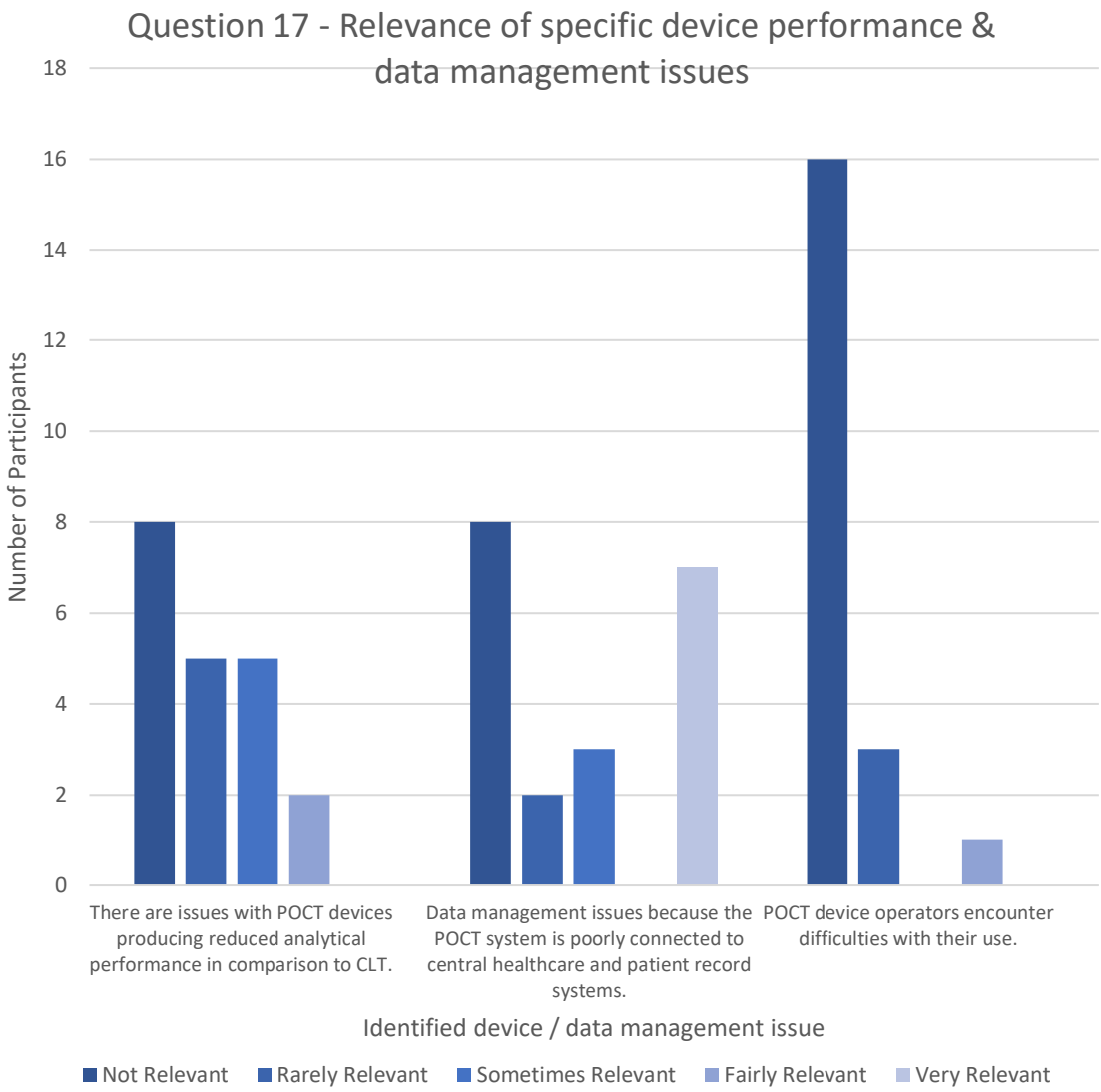

Figure 5.15 - Clinician opinion on the relevance of specific device performance and data management issues within their clinical environment (n=20).

5.3.4 Staff & Operational Issues

The final category considered within this study was that of staff and operational issues with respect to the utilisation of a POCT system. One of the key issues in this respect was that of the workload of front line clinical staff who are the operators of POCT devices in practice, and in particular the impact that this has on their effective utilisation. The pool of opinion here, as summarised in Figure 5.16, indicates a modest level of agreement with this proposition, with 5% of respondents stating that they "agree" and a further 9% that they "strongly agree" with the use of POCT significantly increasing the workload of front line clinical staff. Conversely, 38% of respondents were seen to be "strongly disagreeing" with this statement, while a further 24% "disagreed". The remaining 24% of participants gave a "neutral" response in this instance. Much of the dialogue attained from study participants supported the opinion that POCT did not significantly increase the workload of device operators. Comments in this regard included:

- *"POCT is not used efficiently here. If a certain parameter is needed quickly, POCT will be used to attain this, but a blood sample is always taken and sent to the laboratory for further parameters anyway, even when they are available through the use of the point-of-care test already carried out. Therefore, the staff are taking blood as they would be doing anyway."*
- *"Staff would be doing the same amount of work anyway by taking blood samples and chasing up the laboratory for results."*
- *Sending samples to the laboratory requires time in chasing up the results so there is no significant addition with POCT."*

It should be noted that the small number of participants (n=3) who "agreed" or "strongly agreed" that there was a significant increase in workload as a result of the use of POCT all were of the opinion that this reduced staff satisfaction levels in comparison to utilising the traditional CLT method. The reasoning behind this was that front line clinical staff wanted to be involved directly in patient care and that the operation of POCT was seen as a hindrance and a distraction from this ideal.

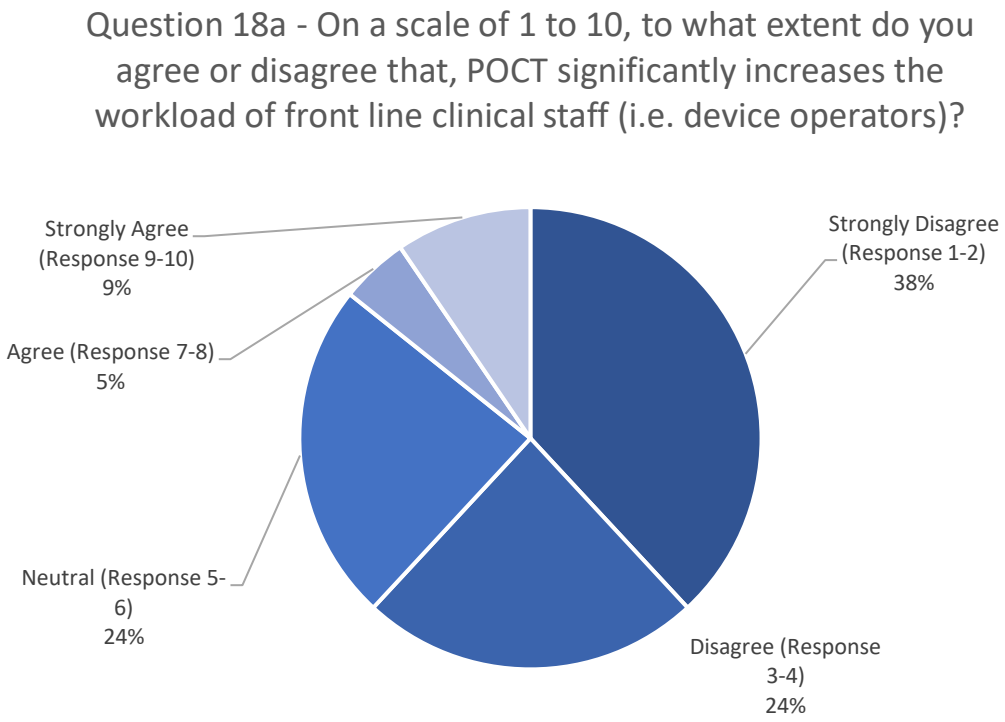

Figure 5.16 - Clinician opinion of the impact of POCT use on the workload of device operators (n=21).

A significant issue identified from the literature review outlined in Chapter 3 was the perceived reluctance of the central laboratory to allow the control of testing to be passed to users. The participant response to this proposition for the US clinician study, as summarised in Figure 5.17,

was significantly varied, as it was also found to be the case for the data from the UK study. A substantial proportion of the study group were of the opinion that the central laboratory was indeed reluctant to allow the control of testing to be transferred to the clinical environment, with 32% of respondents "agreeing" and a further 26% of respondents "strongly agreeing" with this statement. The corresponding "neutral" responses and those in "disagreement" were found to be relatively low (11% and 5%, respectively), with 26% of respondents "strongly disagreeing" with this statement.

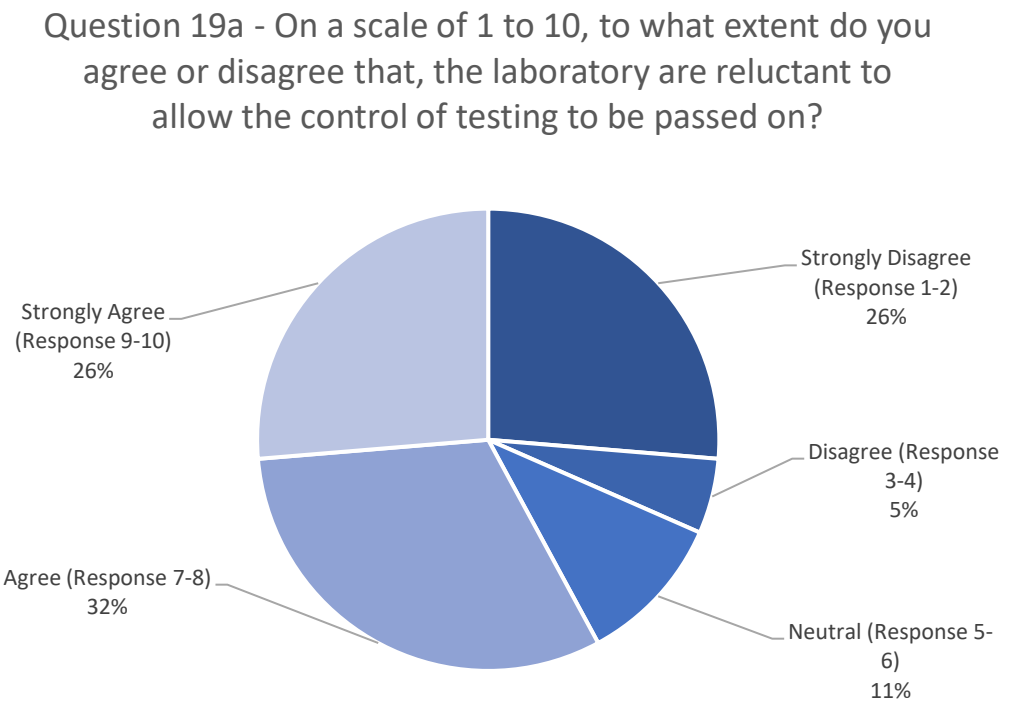

Figure 5.17 - Clinician opinion on the reluctance of the central laboratory to release the control of POCT testing to the clinic (n=19).

Comments made by the US clinicians who were in agreement that this reluctance exists, suggested that this was as a result of the CLIA regulations rather than a stance being made by those in the central laboratory themselves, and that these regulations have been imposed in order to protect the role of the central laboratory as an entity throughout the entire US healthcare system. Interestingly, comments made by participants from the clinical biosciences cohort indicated that there was belief that this reluctance was a necessity. Comments in this regard included:

- *"Letting someone else control quality is a risk if they are not trained in laboratory methods. There is evidence that non-laboratory operators are more prone to error."*
- *"Nursing staff don't understand laboratory tests and if a clinical decision is made on an incorrect result then it is considered a lab test that has gone wrong."*

Of the 11 responses that fall within the “agree” or “strongly agree” category, 9 were of the opinion that this reluctance acts as an impediment to the more widespread adoption of POCT within the near patient clinical environment in the US. One participant noted that this was especially true within the outpatient setting.

As illustrated by Figure 5.18, when clinicians were questioned on the clinical care pathway and the role of the central laboratory and the extent that these had been altered in order to accommodate POCT, participant response was fairly evenly split across the scale. The “strongly disagree” response represented 20%, with 10% as “disagree”, 20% as a neutral response, 30% “agree” and the remaining 20% as “strongly agree”. Focusing on those who “strongly disagreed” that sufficient alteration to the clinical pathway had been made, there would seem to be 2 interrelated reasons for their responses, based on comments made by clinicians. Firstly, there was an opinion that the current system that involves joint responsibility for quality between the laboratory and clinicians does not work as there is no clear line of responsibility. Secondly, there was an opinion that alteration to the clinical pathway was not required as POCT should simply be used in time-critical situations where and when it is needed, and not as part of the standard clinical pathway in place of the traditional CLT service. Of the 6 participants who “disagreed” or “strongly disagreed” that sufficient accommodation had been made, it is interesting to note that 2 believed this situation did not affect their ability to attain a timely and reliable diagnosis in comparison to utilising CLT.

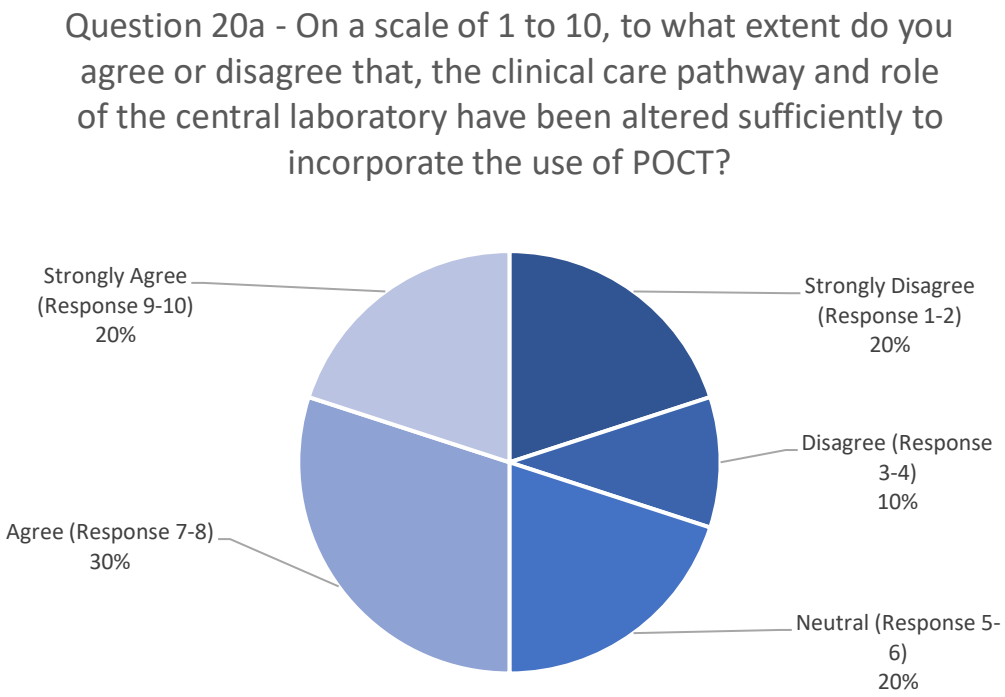

Figure 5.18 - Clinician opinion of how the clinical care pathway and role of the central laboratory have to be altered to incorporate the use of POCT (n=20).

The relevance of other specific issues in this category of possible impediments to the adoption of POCT were investigated in terms of how they affected participants in their specific place of work. Specifically, 6 issues were explored and results presented in Figure 5.19. The dominant issues were; reduced staff satisfaction levels and friction between staff groups as a result of POCT usage; inappropriate use of POCT including over-use and a reliance on test results undermining clinical expertise; a failure to attain potential benefits through POCT use due to significant alterations to the clinical care pathway and the role of the central laboratory in this regard, and; inefficiencies in the use of POCT due to the requirement for an interdepartmental management structure with clear clinical governance. Importantly, the most pronounced opinion attained through this study alluded to the fact that POCT was actually under-utilised rather than over-used. Comments made by clinicians explained this perspective further and included:

- *"We could be doing more POCT but people are risk averse and send samples to the lab instead, sometimes even if there is a clear clinical benefit to utilising POCT."*
- *"Over-use is a risk but it is unlikely to happen due to a lack of reimbursement for POCT."*
- *"POCT could help in a lot of situation but a lack of training means some operators don't understand when to utilise it for full benefit."*

Although the "not relevant" response was the most common with respect to the reluctance of the central laboratory to release control affecting the more widespread uptake of POCT (7 responses), there were also 5 responses that indicated that this was either "fairly relevant" or "very relevant".

The final issues studied in this category addressed difficulties implementing POCT due to a reluctance to change and a lack of evidence justifying the utility of POCT. Opinion here was substantially varied but there was enough data to suggest this is a relevant issue in reality within the US healthcare system; 5 responses indicated that this issue was "not relevant", 6 clinicians signified it to be "fairly relevant", and a further 5 clinicians were of the opinion that this particular issue was "very relevant" to them within their area of practice. Comments made by participants that allude to this perceived reluctance to change include:

- *"There is a lot of inertia. Logistics, workflow, financial and territorial considerations always come before actual clinical benefit."*
- *"There is resistance towards moving extra work towards nursing staff."*
- *"Not a lack of evidence but a big resistance to change."*
- *"We had to perform our own side-by-side comparison between POCT and CLT to prove the system as there was not enough evidence."*

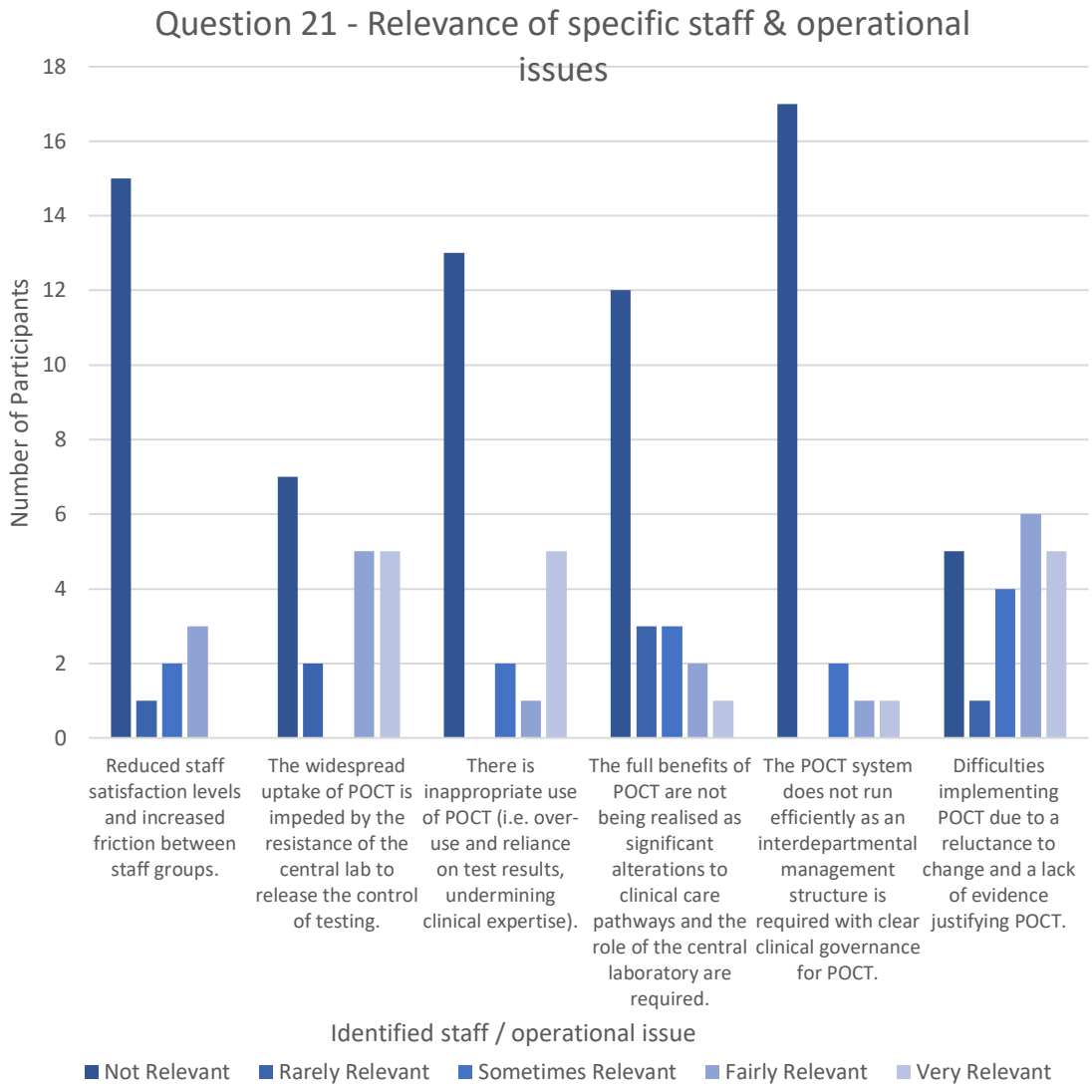

Figure 5.19 - Clinician opinion of specific staff and operational issues within their own clinical institution that affect the use of POCT (n=21).

5.3.5 Other General Issues

Outside of the main categories of enquiry, participants were questioned from a more general perspective with regard to their opinion of the real value of POCT. In this section, participants were afforded the opportunity to answer more freely through text boxes rather than numeric scales and tick-boxes. The focus in the first instance addressed the main advantages offered by POCT when compared to CLT usage. The responses attained are summarised below in order of the frequency with which each occurred:

- Rapid turn-around-time (TAT), resulting in a quicker decision/diagnosis and earlier clinical intervention (93% of respondents).
- Improved patient/operator satisfaction and convenience (37% of respondents).

- More efficient patient management (30% of respondents).
- Improved quality of care and better patient outcomes (19% of respondents).
- Avoidance of sample transfer where there is no laboratory on site or within close proximity (7% of respondents).
- Help to meet political targets i.e. TAT targets and patient waiting times (7% of respondents).
- Provides the ability to the clinician to repeat tests (7% of respondents).
- Less reliance on a chain of services where delays are more likely (7% of respondents).
- Ease of use (7% of respondents).
- Cost savings (7% of respondents).
- Improved reliability and accuracy (7% of respondents).
- POCT provides a good backup service when laboratory or sample transport systems are down (individual response).
- Avoidance of sample stability issues during transport (individual response).
- Transfer of some of the laboratory workload to the wards (individual response).
- Provides control of when the sample is tested to the clinician and the opportunity to perform serial testing (individual response).
- Overcomes problems of poor access to hospital/medical care (individual response).

As was the case for the UK study (Chapter 4), the overwhelming response was that of a rapid TAT, resulting in a quicker decision/diagnosis and earlier clinical intervention, as indicated by 93% of clinicians within the study. Improved patient/operator satisfaction and convenience along with more efficient patient management were both again found to be significant advantages, denoted by 37% and 30% of participant response respectively.

The main disadvantages of POCT usage in comparison to utilising CLT was then considered. Participant response in this case is summarised below, again in order of the frequency with which each occurred:

- Poor quality/inaccuracy of results obtained by untrained or non-competent staff and the consequent risk to the safety of the patient (30% of respondents).
- Staff training requires a lot of time (22% of respondents).
- Increased costs (22% of respondents).
- Reduced accuracy compared to CLT and duplication of tests carried out by the central laboratory (22% of respondents).
- Quality management requires significant resources and is difficult to control due to dispersed nature of the devices (19% of respondents).

- Inappropriate use, i.e. over-use and reliance on (POCT) results undermining clinical expertise (19% of respondents).
- Difficulty in ensuring continued staff competency and unfamiliarity caused by a lack of regular use (19% of respondents).
- Lack of connectivity to central healthcare and patient record systems (19% of respondents).
- Takes up a lot of staff time (15% of respondents).
- Results and subsequent interpretation highly dependent on operator competency (11% of respondents).
- Requires awareness of limitations otherwise their use is dangerous (7% of respondents).
- Difficult to reach the standard of CLT as it is difficult to control a range of staff/departments/management structures in comparison to control within the confines of the laboratory (7% of respondents).
- Auditing and clinical governance is difficult due to fragmentation of the service; lines of accountability are very unclear (7% of respondents).
- Lack of a specific budget for POCT (individual response).
- Little support from senior management for POCT (individual response).
- Requires buy-in from other departments which is often hard to attain (individual response).
- Financial benefits are difficult to prove, despite an improvement in patient care (individual response).
- Specific skills are required to perform POCT and so it may not really be a 24-hour service (individual response).
- Added responsibility on another healthcare professional with regard to calibration, ordering of test strips, etc. (individual response).
- Maintenance of devices is difficult (individual response).

Clearly, the most common response here was that of poor quality/inaccuracy of the POCT results that may be obtained by untrained or non-competent staff and the consequent risk to the safety of patients that this brings, as indicated by 30% of respondents. Interestingly, the frequency of this response is significantly less than that associated with the main advantage of POCT, i.e. improved TAT.

When asked for their opinion on where POCT can be best utilised within the healthcare system, and more specifically which diseases and/or conditions benefited most from its use, the frequency of the collated responses was as follows:

- Respiratory conditions, i.e. blood gas testing (70% of respondents).
- Diabetes, i.e. blood glucose testing (70% of respondents).
- Blood coagulation, i.e. International Normalised Ratio (INR) monitoring (48% of respondents).
- Cardiac conditions, i.e. cardiac marker testing (30% of respondents).
- Sepsis testing, i.e. blood poisoning or septicaemia (19% of respondents).
- Urine pregnancy testing, i.e. in ED or surgery (19% of respondents).
- Other blood tests, i.e. HBA1C, lactate, etc. (19% of respondents).
- Monitoring of foetus condition during pregnancy (15% of respondents).
- Drug abuse (15% of respondents).
- General trauma and internal bleeding, i.e. emergency conditions (11% of respondents).
- Brain injury and critical care patients, i.e. ventilated (7% of respondents).
- Gastroenterology (individual response).
- Patients with mental health issues (individual response).
- General surgery (individual response).
- Hypotensive patients (individual response).
- Influenza (individual response).
- Infectious diseases in developing countries (individual response).

As above, the 2 most frequent responses here can be seen to relate to the value of POCT in the diagnosis/monitoring of respiratory conditions (i.e. blood gases) and diabetes (i.e. blood glucose monitoring), with both having been indicated by 70% of participants.

The ultimate objective in gaining an understanding the barriers to the adoption of POCT is of course to provide a way to overcome them. Therefore, it was deemed important in this study to gain clinicians feedback on how this could be potentially achieved. Study participants were therefore asked directly to suggest possible solutions to overcoming any of the real and/or perceived barriers to the adoption of POCT technologies. The frequency of the responses received were as follows:

- Audit the use of POCT to provide evidence of clinical and/or economic benefits to stake holders as a way to overcome issues such as mistrust of POCT and a lack of full backing for its implementation by the healthcare system (41% of respondents).
- Better connectivity to central healthcare systems and interfaces (26% of respondents).
- Increased laboratory support for implementation and after-care, i.e. a dedicated team to look after QA in POCT (26% of respondents).

- Improved training processes, including re-training and mandatory centralised training (19% of respondents).
- Reduced costs from manufacturers for both the devices and their implementation via a form of a central POCT funding (19% of respondents).
- Closer collaboration between the clinical and support areas involved (19% of respondents).
- Improved QA processes and auditing processes for POCT to ensure confidence in them (19% of respondents).
- Regional consensus/strategy on POCT procurement (15% of respondents).
- Treat the introduction of POCT tests in the same way as that employed for the introduction of new drugs, i.e. through a proper change management project (7% of respondents).
- Increase availability of POCT though the healthcare system (7% of respondents).
- Increase use of POCT in primary care (individual response).
- Give feedback on POCT performance to stakeholders following its implementation (individual response).
- Improve user-friendliness of devices (individual response).
- Adopt a more streamlined path from device development to clinical use (individual response).
- Manufacturers should be encouraged to provide free pilots of POCT systems so that benefits can be witnessed first-hand (individual response).
- Increased transparency of governance arrangements and expectations throughout the application process for the deployment of such devices (individual response).
- Restrict the use of POCT to controlled environments, i.e. specialist clinics; based on the fact that 24-hour access machines are difficult to regulate and there are issues with ensuring the competency of operators (individual response).

As was found to also be evident from an analysis of the response obtained in the UK study, the most frequent suggestion made by US clinicians was that overcoming barriers to POCT adoption requires evidence of the clinical and/or economic benefits in order to overcome issues such as laboratory mistrust and a lack of full backing by the health system, as cited by 41% of participants.

A further area of assessment made relates to the importance of the categories of barrier that impact upon POCT uptake in the US healthcare system. Respondents were asked to rank the 4 main categories of barrier identified from the systematic literature review study (i.e. economic, quality assurance & regulatory, device performance & data management and staff & operational

issues), with 1 being most important in regard to POCT uptake and 5 least. The resulting data was managed using a tiered scoring system to attain a final ranking order, where a category would receive 4 points for a first-place ranking, 3 for a second-place ranking, 2 for a third-place ranking and 1 point for a fourth-place ranking. The scoring frequencies of the resulting responses are provided in Figure 5.20.

As seen here, economic issues were found to be the category that has the most significant impact on POCT uptake, with a score of 65, while the staff & operational issues and quality assurance & regulatory issues were ranked closely together with scores of 48 and 46 respectively. Device performance & data management issues were found to have least impact with a score of 41.

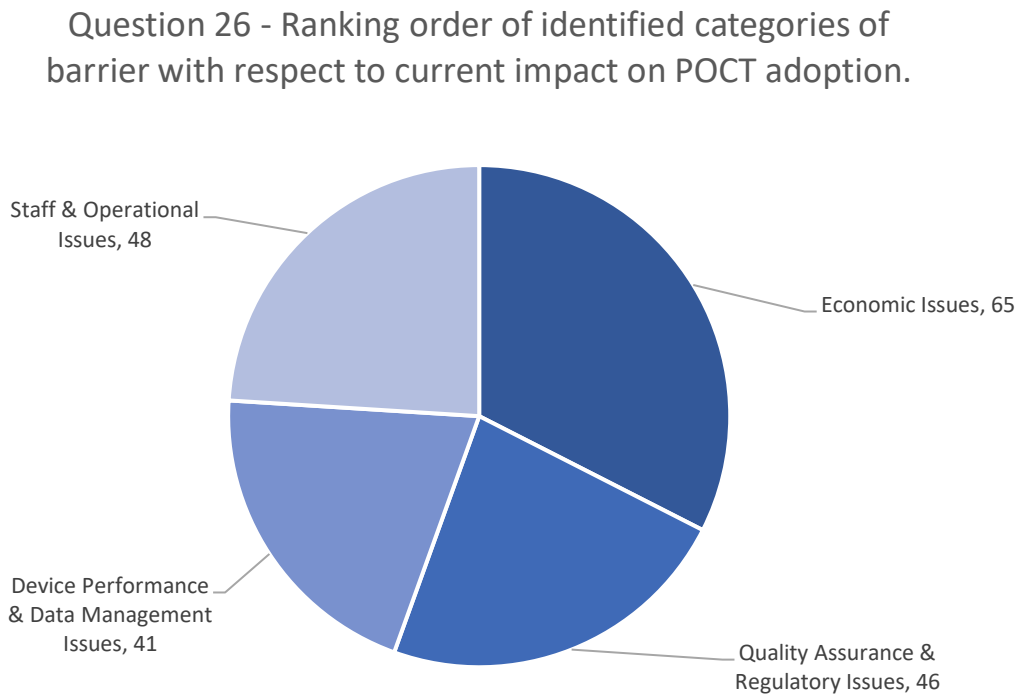

Figure 5.20 - Clinician opinion on the ranking of important of the main four categories of barrier to adoption of POCT as identified from the systematic literature review (n=21).

The final area of evaluation here incorporated the extra question posed to participants in this study with respect to the UK study carried out in Chapter 4. The clinicians taking part in this study were asked if they were aware of any differences between the UK and US health systems that could affect the uptake of POCT within the clinical environment. The comments offered by clinicians are as follows:

- *"Very wasteful of money in the US. There is very little regulation on the tests that doctors order. The efficiency of tests is not considered by the health system, only cost. There is better data on efficiency of healthcare decisions in the UK. In the US, they do not want*

to take on more costs, but nobody is looking at the overall efficiency of the system. Insurers look at the increased cost per test of POCT and do not want to pay for it."

- *"The US system does not have socialised medicine. Many patients don't have insurance or have poor insurance, and so the tests which doctors decide on can come out of the patient's pocket."*
- *"The UK has more ability to make centralised systems - electronic record systems are nationwide. In the US, patients are very demanding and essentially, they drive the changes that they want. In the UK, there is better team-based healthcare but in the US the MD (medical doctor) does huge majority of work."*
- *"In the UK if it makes clinical sense to do it then you can do it. In the US, there is the additional hurdle of if the insurance covers the test or not. Using POCT may result in hospital not being paid - the central lab is much easier to track and bill. The UK system is more self-regulated, the US is more imposed by insurers and therefore individuals are less aware of cost-effectiveness than UK."*
- *"Things which work well in other countries take a long time to get FDA (Food & Drug Administration) approvals in the US and so this causes delays in getting new technologies to patient care."*
- *"In the US, manufacturers are trying to push tests into practices even though they aren't medically the best solution."*
- *"Current healthcare reform (Obama Care) in the US means that any changes must conform with this process - POCT can help with the change to reimbursement on outcomes rather than the number of tests as physicians will be more interested in quick outcomes, however the current changes already in place will make it difficult to implement additional changes to bring POCT in further."*
- *"The costs of testing to the patient in the US private system is the main difference that can affect the uptake of testing."*
- *"There have been huge changes already in the US with "Obama Care". The UK is more practical and cost-conscious, there is much less ordering of unnecessary tests and more use of clinical judgement. Fear of litigation in the US discourages POCT use."*
- *"The UK is more cost sensitive. The US has more variability between hospitals, but trends will be same in both; pockets of high adoption in the small areas where POCT is necessary."*
- *"The UK is more centralised than the US. In Europe, it is much easier to get devices approved. Australia is about 10 years ahead of the US in terms of sports medicine devices."*

- *"Cultural differences are important - The US public like pills, India like injections, other places like tests. The NHS is a centralised model, i.e. if the wrong antibiotics are given then they are picking up the cost and they are also acting as the insurer. In a closed loop system like this there will be more adoption of anything which will increase the efficiency of care. In the US, increased efficiency does not mean increased income for the hospital."*
- *"In the UK, there are limits i.e. what can be done for a certain patient in a certain age group. US there are no limits to the care that can be given."*
- *"US don't have socialised medicine, it is very much fee for service. Money prescribes what we do here to an extent. Lawsuits are a worry over here. In a capitated system here, a physician is given a lump e.g. $10,000 to keep a patient healthy for a year, and keep the excess so there is a big incentive to keep a patient healthy and reduce hospital visits and diagnostic tests. POCT can help with this."*
- *"Funding in the UK is centralised and so easier to calculate savings and costings. The US is very fragmented and so here it is easier to have winners and losers through the system."*

5.4 Discussion

The data collected by the completion of this US based clinician study has been used as a comparison to that attained from the findings from the UK Healthcare service study presented in Chapter 4. The overall objective here is to determine the effects, if any, that national location and/or the underlying healthcare payment model of the relevant health system have on clinical opinion of the value and utilisation of POCT devices within the hospital environment.

An understanding of the wider-ranging issues in terms of healthcare model make-up can be attained by analysing comments made by clinicians to the extra question added to this study relating to differences between the UK and US health systems that could affect the uptake of POCT. The 2 main areas of focus indicated here by clinicians were that of costs and the "centralisation" of healthcare. It has been found that, in the opinion of participants in this study, the UK system of healthcare is much more focused on the efficiency of delivery in comparison to the US. Whereas, the UK system can make decisions based solely on "clinical sense", the insurance model in the US has been described as an "additional hurdle" with respect to delivery of care. The capitalist-driven system of the US means that the delivery of care is directed much more by the patient and/or insurer. As a result, those who can afford medical care are actually better off than a UK patient. However, the UK system provides the same level of care to all, without exclusion, meaning all UK patients are better off than an individual in the US who can't afford medical care (Marsden 2006). It has been indicated by participants in this study that many insurers will not want to pay for the increased cost per test of POCT in comparison to CLT

within the US health system. As such, overall efficiencies are often ignored in this respect. Furthermore, it has been suggested that patients with poor or no health insurance coverage will not want to make use of POCT as the increased cost will be coming out of their own pocket. Hence, the UK model, free at the point of delivery, is thought to be much more self-regulated than the US, in which, according to the clinicians interviewed, there is very little regulation of tests ordered by doctors. According to the base of opinion gathered by this study, this results in individuals within the US health system being much less aware of the cost-effectiveness of healthcare provision. The US has been found to spend the most per capita on healthcare of any country in the world and yet has failed to match the advances in population health of other wealthy nations (US Burden of Disease Collaborators 2013). From a top-down perspective, this indicates the operation of an inefficient system.

Clinical opinion here also indicates, perhaps unsurprisingly due to the geographical disparity in terms of size, that the UK system is much more "centralised" in comparison to that in the US. For example, it was suggested in this study that nationwide patient record systems exist almost everywhere in the UK while they are often not available in the US. In 2012, it was found that only 44% of hospitals in the US had implemented what was considered to be at least a "basic level" electronic patient health record system (DesRoches, Charles et al. 2013). Hence, the implementation of new technologies on a national scale is more difficult in a substantially more fragmented system such as in the US. It is also thought that the more disjointed nature of the US system results in a much slower process in terms of regulatory approval of new technologies, with 1 clinician indicating this while adding that "*Australia is about 10 years ahead of the US in terms of sports medicine devices"* for this reason. While the US system of approval has faced criticism, mainly from industry, for being too slow, risk adverse and expensive, the European system of approval has also faced criticism, despite being a much faster process. This has centred around the notion that the European regulatory framework of using the Conformité Européenne (CE) Marking process is not sufficient in terms of providing adequate safeguards for devices directly impacting upon morbidity, mortality and health related quality of life (Sorenson, Drummond 2014).

In terms of the barriers to POCT uptake, economic issues are found to be most prevalent amongst US clinicians. Whereas, within the UK health system the categories of economic issues and quality assurance & regulatory issues received equal ranking, those working in the US health system found that the economic issues were more significant in regard to impeding the adoption of POCT.

Economic issues were found to be highly significant in terms of impact upon POCT uptake in both studies thereby providing evidence of its influence regardless of the payment processes

operating within the healthcare system concerned. A noteworthy difference in the US and UK clinical opinion is seen with regard to the cost per test of POCT. Those who participated in the US study were very unclear as to the real cost per test of POCT in comparison to CLT, with a higher percentage (43%) of clinicians disagreeing that POCT introduces increased costs than agreeing (33%). By comparison, the majority opinion in the UK study (75%) was that POCT was indeed more expensive than CLT on a cost per test basis. Based on comments made by study participants here, it is possible that their opinion is influenced by the levels of reimbursement found within the US healthcare system and the privatisation of central laboratories. It would seem that in many cases, reimbursement is made for laboratory tests and that POCT is incorporated into this process, i.e. as a responsibility of the central laboratory, and so receives the same level of reimbursement as the equivalent CLT, which tends to be minimal. As a result, from the clinician's point of view, the cost of a specific test has no difference to them whether it is performed by CLT or POCT. Privatisation of the central laboratory service can in some cases cause CLT to be more expensive to the patient than POCT, according to opinion attained in this study. Outsourced central laboratory services can also be significantly inconvenient for the patient. For example, a clinician in a fully equipped hospital may order a test for a patient, however the insurance company employed by the patient may insist on the test being carried out and a particular private facility, therefore resulting in the patient having to travel elsewhere for the test to be carried out. This problem is especially relevant for outpatient situations (Chasin, Elliott et al. 2007).

The insurance-based costing model operating in the US healthcare system can also affect the reimbursement of tests. For example, according to participants of this study, certain insurance providers recommend the use of particular tests (or brands of test) and do not provide full payment if this advice is ignored. This would appear to be in line with the situation of pharmaceuticals in the US, where levels of cover vary between different insurers based on FDA approvals and the patent status of drugs i.e. branded/generic (Stephane A. Regnier 2014). As a result, the specific insurance policy that a patient has directly affects the types of tests that can be performed as part of their care (based on their availability within the hospital). Hence, the cost to the hospital in terms of testing can vary considerably on a patient-by-patient basis. It is interesting to note that the movement towards global payments made through DRGs (Diagnostic Related Groups) is very much taking place within the US healthcare system with many of the clinicians participating in the study alluding to this development. This agenda results in a hospital receiving reimbursement based on the resolution of an episode, rather than the traditional cost-based system of reimbursement where the hospital gets paid based on the number of tests performed. Therefore, although the cost to the clinician is equal in terms of comparing POCT and CLT, the method of reimbursement will be provided based on the outcome

and not the path used to get there. It was noted by a proportion of participants in this study that the inappropriate use of POCT was a relevant issue within their place of work, i.e. over-use and reliance on test results which can undermine clinical expertise which is an issue that DRG-based payments could rectify. However, clinicians also alluded to the fact that this was not an issue specific to POCT, but rather was relevant to all types of testing. As was observed in the responses for the UK study, the clinicians here were generally of the opinion that use of a POCT system was cost-effective. It was stressed by a US cardiologist participating in the study that it's important to note that POCT is not cost-saving, but is cost-effective, in the way that it makes good use of any extra expense that may be incurred as a result of its use.

Whereas some of the potential solutions to understanding and overcoming economic issues associated with the use of POCT can be translated easily from the UK system to the US healthcare structure, there are some difficulties due to the insurance-focused nature of the latter system. For example, it would be much more difficult to implement a centralised POCT budget within hospitals in the US due to the influence that insurers have on the types of tests carried out and the privatisation of the central laboratory in many institutions. However, common themes were relayed here in this respect of a solutions-based approach that were of a similar nature to those found by the previous UK study. In particular, the need to produce a stronger base of evidence regarding clinical outcome improvements that POCT can provide that would justify any costs incurred in their implementation or operation was common to both jurisdictions.

Due to the obvious variations between the UK and US systems in terms of how healthcare is funded, differences of opinion on the economic considerations of POCT were somewhat expected. However, an investigation of the other categories of barrier to POCT adoption can help ascertain whether or not the overarching model of healthcare has a direct impact on clinician opinion and to what extent this prevails. For example, it is important to determine whether quality assurance & regulatory issues are regarded equally by those working within the 2 different systems or if local/national considerations can have a significant influence on the clinical technologies utilised. POCT is expected to grow steadily in the early part of this century (Scalise 2006) and, in doing so, become a more integral part of healthcare management. As a result, expansive quality assurance protocols are required to optimise patient care and the efficiency of healthcare delivery (Larsson, Greig-Pylypczuk et al. 2015). While traditional CLT has had quality assurance protocols in place for many years as part of regulatory frameworks imposed upon the diagnostics sector, POCT has been viewed differently by manufacturers in that it has been developed specifically to be used by clinicians rather than trained laboratory professionals. Consequently, the POCT devices do not fit well with the traditional quality control

procedures (Martin 2008). Regulatory requirements often mean that existing quality protocols must be still be applied to POCT or adapted as best possible.

In line with what was discovered from the analysis of responses to the UK study, it was found that US clinicians from the clinical biosciences cohort were of a strong belief that the decentralised nature of POCT devices leads to increased opportunities for their use by untrained or non-competent staff, leading to an increased disregard for certain quality assurance steps and procedures, including quality control. While opinion in general was significantly varied with respect to this particular issue, 4 study participants from this clinical group gave an average response of 8.25 in this study on the 10-point scale used to attain a measure of agreement. The reasons for this are likely to be the same as suggested for the UK health system, with quality control inside the central laboratory being a direct responsibility of the highly skilled individuals who operate sophisticated instruments which are long embedded within health system processes. By contrast, quality control for POCT devices is much more difficult to deliver with a significantly higher number of users, often analytically unskilled and utilising less sophisticated devices. Although this particular issue was found to be of little relevance to the participants within the study, those clinicians who did cite it as an issue alluded to the fact that there is no monitoring system in place to ensure quality assurance in POCT and so errors are only ever caught if they are reported through official channels after the event, which often they are not. One such participant indicated that CLIA waived tests were of most concern due to the fact that individuals did not need a lot of training to be able to utilise them. US congress passed the CLIA statute in 1988 in order to establish quality standards in laboratory testing. This statute made provision for tests to be waived from regulatory oversight if certain requirements were met. In order to be waived, tests must employ methodologies so simple that the likelihood of result error or harm to the patient through incorrect use is negligible (Bode, Irvin et al. 2007). As such, operators with little or no training hence have access to waived POCT devices and the opinion of the clinician in this case was that their use can yield a higher risk of quality issues occurring in practice.

Opinion was attained on how such complexities in the regulations for analytical testing accreditation can affect the use of POCT. While opinion in general was varied, a clinician indicated that the manufacturer of a particular POCT glucose test does not recommend its use for critically ill patients. Therefore, this device that is CLIA-waived in most areas within the hospital is promoted to non-waived status within the Intensive Care Unit (ICU). As a result, a device which requires just very basic training to operate in the majority of clinical areas within the hospital system requires significantly increased operator qualifications for use within this particular department which many of the nursing staff do not possess, deeming it unusable in

many cases. It is clear that a situation could therefore arise where a particular operator can utilise the device within one department, but then be prevented from utilising the same device in another department due to regulatory issues. It is obvious that this could then act as an impediment to the uptake of such devices within a hospital or other healthcare environment. Hence, regulatory issues such as this should be addressed accordingly in order to standardise required operator qualifications across all potential departments of use.

Another issue identified with respect to the accreditation regulations was difficulties in maintaining compliance as a result of the dispersed nature of this type of diagnostic testing. A significant proportion of respondents here (36%) indicated that this issue was either relevant or very relevant to them in their area of practice. One clinician gave a specific example to explain this; glucometers are used within 2 locations in the clinician's place of work by over 3000 nursing staff (who operate them) thereby making them very difficult to control. It should also be noted that 6 clinicians did not answer questions regarding specific regulatory issues (13b, 13c, 13d) due to a lack of knowledge on the area. This type of response was also observed in the UK study and hence it is apparent that individuals who operate such devices within both the UK the US healthcare systems would benefit from increased education on the particular regulatory requirements that pertain to their use. It is imperative that, for a dispersed POCT analysis system, there is increased awareness of regulatory requirements hospital-wide, rather than the knowledge being held solely by those who are responsible for the application of such regulations i.e. the central laboratory services. However, a fundamental difference between the US and UK healthcare systems that may be significant in this respect is that the privatisation of central laboratories within the US system may lead to education on regulatory requirements being held back from those responsible for operating such devices. One US clinician involved in this study indicated that the central laboratory, being a private entity, saw POCT as direct competition. Private laboratories are operated with the purpose of making profit, and if POCT is perceived as a threat to this then it will not be actively supported. There has been a growth in the outsourcing of healthcare operations in the US in this millennium, with around 75% of US hospitals now having at least 1 outsourced function (Guimares, de Carvalho 2011). Due to the widespread privatisation of such facilities throughout the US, this has the potential to be very damaging to the more widespread uptake of POCT within hospitals.

As was also the case in the findings from the UK study, in terms of overcoming quality and regulatory related issues, improved training processes was found to be a common suggestion offered by participants in order to negate the risk of untrained or non-competent individuals operating POCT devices. Improved quality assurance processes, along with a dedicated team to oversee of this, was also found to be a common theme for improvement in the US system, again

mirroring the opinion attained from UK clinicians. Moreover, the identified need for increased support from the central laboratory should be incorporated into this improvement of the appropriate processes. However, it is recognised that an avenue to gain support from privatised labs must be investigated to ensure adequate support is given.

The quality issues associated with the use of POCT have been linked in the past with the usability of such devices (Crook 2000, Linder 2007, Goodwin 2008), however the US clinicians involved in this study were overwhelmingly of the opinion that POCT devices were easy to use. It can therefore be deducted that POCT devices have developed to the extent that usability is no longer an issue in terms of uptake, and has no or little influence upon the quality of the test results obtained. Issues relating to the quality of test results can be due to human error and hence are not fundamental characteristics of POCT itself, but actually components of how the device is utilised in practice.

Similarly, the analytical performance of POCT has historically been linked with quality assurance aspects of their utility (St-Louis 2000, Perry, Fitzmaurice et al. 2010, Murray, Fitzmaurice et al. 2004, Melo, Clark et al. 2011). However, like the UK clinicians studied in Chapter 4, the US clinicians have indicated that POCT is generally regarded as providing an acceptable level of diagnostic data in comparison to CLT. Participants here alluded to the fact that, within the US health system, POCT is regarded more as a screening test rather than a standalone diagnostic solution and so analytical performance did not need to be to the same standard of instruments found within the central laboratory.

One distinct difference between the UK and US studies was with regard to the connectivity of POCT devices in that clinicians within the US study indicated that levels of connectivity varied significantly across the hospital with some departments able to enter results directly into electronic records, while some departments rely on the manual method of physically writing results into records. It was interesting to note that all of the 7 respondents here who indicated that connectivity was “poor” or “very poor” signified that this lack of connectivity made it difficult to attain a timely and reliable diagnosis in comparison to utilising CLT. This is a significantly different finding to the expressed in the UK investigation where 25 of 33 respondents indicating that connectivity was “poor” or “very poor” were of the opinion that the connectivity issues did not make it more difficult to attain a timely and reliable diagnosis (in comparison to CLT). The main issue for the US clinicians seemed to be with respect to the loss of access to diagnostic data via the patient record systems when using of POCT. The loss of access to this data has the potential to act as a significant barrier to uptake of POCT as it can make its use seem undesirable to a clinician who often requires as much data as possible to make appropriate clinical judgement on a situation which is often complex and time-critical. The

reason that the issue of connectivity seems to be more significant in the US health system may be due to the privatisation of central laboratory services and the ensuing lack of updating of patient records that can result. Canada also utilises for-profit corporations to provide medical laboratory services for a proportion of its healthcare system, and these have proved to cause difficulties in terms of integrating patient records, with the private laboratories operating their own standalone record systems (Sutherland 2012). Opinion on the role of connectivity here was more varied than in the UK study and suggests that the US healthcare system has done more to improve connectivity of POCT devices within local healthcare networks. However, it is the case that when connectivity is not of an adequate standard then this has an increased impact upon diagnostic services in the US compared to the UK healthcare system, where central laboratories are nearly always part of the same body. Therefore, perhaps unsurprisingly, improving the connectivity of POCT devices within the patient record system was found to be a common suggestion by clinicians within this part of the study with respect to overcoming barrier to the more widespread adoption of the devices.

Further to improved connectivity with central patient record systems, there have been indications from literature of issues with respect to how POCT interacts with the structure of healthcare organisations and the dynamic of staff and staffing groups within these processes, with 18 articles identified by the systematic review (Chapter 3) indicating these issues to act as barriers to uptake of POCT. As was found to be the case for the UK study, POCT was not found to significantly increase the workload of front line US clinical staff. However, the basis for this opinion appears to be different between the 2 jurisdictions. Whereas, in the UK study much of the opinion was based on the fact that chasing the central laboratory for results took up as much staff time as carrying out the tests themselves using POCT, the US study was based on different reasoning. Much of the rationale here was based on the fact that blood samples are taken regardless of which type of test was performed and so utilising POCT does not add any workload to what is already a standard CLT procedure. It would appear that POCT is not utilised efficiently within the US structure, and is generally used when a parameter is needed quickly, i.e. for screening purposes. A sample will then still be sent to the central laboratory for testing of further parameters even though these could often have been attained using the same POCT device. The reason for this approach would seem to be down to clinical trust given that POCT is widely regarded in the US health system as primarily a screening tool and not as a fully-fledged diagnostic tool. For this reason, POCT is only used in time-critical situations where a measurement parameter is needed quickly. If the data is not needed quickly then the result from the central laboratory test will always be used.

With some of the US clinical opinion indicating that POCT is not utilised efficiently, it was not surprising to note that there was also some opinion indicating that the clinical care pathway and role of the central laboratory had not been altered sufficiently to incorporate the use of POCT. Much like in the case of the UK study, opinion here showed a significant variation on this topic. However, some of the opinion received alluded to the fact that the clinical care pathway didn't actually need to be altered. The attitude here was that POCT should not be forced into areas where it is not necessarily needed for a rapid diagnosis, and hence the traditional CLT model should be maintained in the majority of cases. One participant from within the clinical biosciences cohort indicated that such alteration was required as the current model of shared responsibility between the clinicians and central laboratory staff does not work due to a lack of clear line of responsibility. Better defined clinical governance is therefore a key requirement and the clinical laboratory service should therefore ultimately be responsible for the management of POCT devices and attendant data generation. However, controlling such a dispersed range of devices remains the issue and must be addressed if they are to be utilised effectively. The current issues associated with shared responsibility has led to accusations that the central laboratory service is reluctant to release the control of POCT beyond its confines and hence it is this that inhibits their more widespread adoption of such a range of testing (Huckle 2008, Halpern 2000, Fermann, Suyama 2002). Much like the findings from the UK study, opinion here was varied on this controversial issue. Only those clinicians working in the clinical biosciences area of practice tended to consistently agree with this proposition (average response of 6.75 on the 10-point scale, where 10 was strongly agree). It is assumed that this is again mostly due to the perceived risk of allowing clinicians to be responsible for test quality assurance when not sufficiently trained in laboratory analytical methods. One individual from the clinical biosciences cohort noted that if a clinical decision is made based on incorrect POCT results attained by nursing staff, then it is considered a laboratory test that has gone wrong, but that nonetheless, those in the clinical biosciences field are held responsible and so they prefer to keep control of the devices within their own confines. The solution to this issue appears to be improved training processes and increased aftercare support from the central laboratory service as suggested in both this and the UK study. Interestingly, one participant in the US study cohort indicated that the CLIA regulations were set up to keep control within the central laboratory service in order to protect their existence, and it was this fact rather than any reluctance by staff that prevented control from being passed to other clinical groups. It is however likely that regulations are more focused on attaining high quality test outputs and so control of testing will be regulated mostly by this consideration.

In terms of an assessment of the general utility of POCT, US clinicians provided a strikingly similar evaluation to that reported within the UK study. With respect to advantages attainable through

utilisation of this range of testing, a rapid TAT and hence quicker clinical decisions and/or interventions were found to be overwhelmingly the most common benefit provided by participants here. Increased efficiency with respect to patient management and improved satisfaction and convenience for both the device operator and patients were again commonly cited as clear advantages to the use of POCT. No single disadvantage was significantly more common than others, with cost and quality control issues resulting from their use by untrained or non-competent personnel were the more common issues in terms of drawbacks to increased utilisation. Diseases and conditions that benefitted most from the use of POCT devices identified here included areas where they historically been most embedded i.e. blood glucose monitoring for diabetic patients, INR monitoring for patients receiving warfarin therapy and respiratory conditions, as was also the case for the UK study. One participant alluded to the fact that there is a greater demand for POCT to be developed and enter the healthcare sector from influences outside of the national healthcare system in US than within. This particular participant also indicated that the Department of Defence in the US has acted as a massive driver for POCT development, especially since the rise in threat of bioterrorism. Emerging technologies in this regard must therefore be encouraged to enter the healthcare system and be adopted accordingly.

The principal focus of the study described here was to achieve the fifth research objective as defined in Chapter 1; to compare and contrast clinical perspectives (opinions) on those issues that are seen as impediments to the uptake of POCT from clinicians working in the UK healthcare system, i.e. that is free at the point of delivery, with those in the US system where the cost of healthcare provision is insurance-based. As a means to achieve this, primary data attained here has been mapped back onto the findings of the UK-based study described in Chapter 4 and areas where opinion has been influenced by the underlying health model have been identified accordingly. Additionally, the study has collected data to further work toward achieving the final 4 research objectives noted in Chapter 1, namely; to identify the key advantages and potential benefits of POCT use within secondary healthcare; to identify the major disadvantages deemed to result from the use of POCT; to determine the clinical areas/situations in which POCT can provide the most benefit in secondary care; to suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption?

Overall, it is apparent that many of the findings from the US study compare with what was found in the UK study and indeed that many of the pros and cons of POCT are universal across global healthcare systems. Differences in opinion would seem to arise mostly in respect to some issues

pertinent to the payment structures that operate within the respective healthcare systems. In particular, how the central laboratory services are organised are reflected in the different opinions from the 2 studies. Moreover, a disconnect between those responsible for POCT and those who utilise it is apparent in both systems. As such, an international study (negating the influence of regional healthcare systems) was conducted focusing on the role of clinicians within the clinical biosciences cohort in order to compare to the findings of Chapters 4 and 5. This study is described in the following chapter.

5.5 Statistical Comment

As conducted in the previous primary study (Chapter 4), an analysis was undertaken to determine if differences in opinion found between clinical groups were statistically significant. In this study, 2 areas were observed as presenting differences in response profile between the clinical bioscientists and clinicians. Firstly, that the decentralised nature of POCT allowed for increased opportunity for untrained / non-competent users to operate the devices, hence leading to quality assurance issues. Clinical Bioscientists were in stronger agreement that this was the case, in comparison to clinicians. Applying the Chi-square test here, a p-value of 0.247 was found, signifying the difference in opinion observed as not being statistically significant (>0.05).

Similarly, the Chi-square test was applied to the second area where a difference in opinion was observed in this study; regarding the reluctance of the central laboratory to release the control of diagnostic testing. Such as was found the UK-focused study, clinicians here were in stronger agreement with this, in comparison to the clinical bioscientists participating. A p-value of 0.852 was returned in this instance, again determining this as not being statistically significant.

Due to the small sample number in this particular study it becomes more difficult to statistically prove observations as being significant. As a result, it is not possible to rule out that these observed differences in opinion between clinical groups in this US-focused investigation are not simply down to chance.

Chapter 6

Perspectives on Barriers to Adoption of Hospital-based POCT Specific to Clinical Biosciences Professionals

6.1 Study Objective

The research outputs reported thus far have addressed the initial 5 research objectives of this work, specifically; to determine from a systematic review of the academic literature the actual issues that affect the adoption of POCT devices within the hospital-based clinical environment; to categorise the issues identified from the literature as a means of understanding in detail their relative contribution to adoption of POCT devices in the hospital environment; to determine, in order of priority, which issues are currently impacting the adoption of POCT devices within the clinical environment; to determine the relationship between those issues identified from a consideration of the academic literature and the opinions of clinicians within the UK healthcare environment on the same issues, and; to compare and contrast clinical perspectives (opinions) on those issues that are seen as impediments to the uptake of POCT from clinicians working in the UK healthcare system, i.e. that is free at the point of delivery, with those in the US system where the cost of healthcare provision is insurance-based.

Additionally, the previous 2 chapters have somewhat addressed the sixth research objective; to assess how the perception of issues effecting the uptake of POCT, including their impact and relevance, varies with respect to the specific clinical role. As an extension of these findings, this chapter seeks to further address this sixth research objective and to specifically focus on achieving the seventh objective; to determine the global experiences of clinical bioscientists, as the professional group most closely aligned to hospital based diagnostic testing, in relation to the identified barriers to adoption of POCT. The core objective here is therefore to determine the extent to which their opinion on the utilisation and uptake of these devices is influenced by their professional roles and responsibilities.

6.2 Study Development & Design

As the work carried out here is an extension of the research described in the previous 2 chapters, the operational basis remains the same. As such, the configuration of a survey study is identical to that used in Chapter 5 but without any consideration of the location of the clinicians or the healthcare system in which they practice. Hence, the final question added to the study in Chapter 5 regarding the impact of the participant's healthcare system on POCT uptake has been

disregarded for this investigation. In addition, this aspect of the research was carried out solely utilising electronic participation through an online survey tool.

The information provided by the analyses undertaken in the previous 2 studies has indicated that there is a significant disconnect between the opinions provided from clinicians who simply wish to utilise POCT devices and those who are responsible for their safe and effective use in the hospital sector, specifically those in the Clinical Biosciences professional group. Therefore, it was decided to seek opinion from a larger international sample of this clinical sub-group. This part of the work was supported via endorsements and dispersion of the online survey tool link by members of a number of international POCT interest groups in North America, Europe and Australasia. As such, the cohort of responders represents those working in the healthcare systems of Canada, USA, Belgium, Netherlands and Australia. As before, the existing research governance and ethical approvals that comprehensively covered the study were applied.

6.3 Study Results

In total, a sample of 101 individuals from a clinical biosciences background participated in this study. Hence, in terms of data collection this provided a much larger pool of opinion to analyse in comparison to either the UK or US specific general clinical studies that were carried out previously. 88 of the 101 participants noted that POCT is used to diagnose patients in their area of clinical specialism. The sample of clinicians were found to be of high expertise with respect to the practical use of POCT, as illustrated in Figure 6.1, with 56% being “highly proficient” in their use, being recognised trainers in the operation of such devices. A further 19% rated themselves as being “competent” in the use of POCT, with 14% holding a “basic level capability”. Just 11% of clinicians had completed no formal training in the use of POCT.

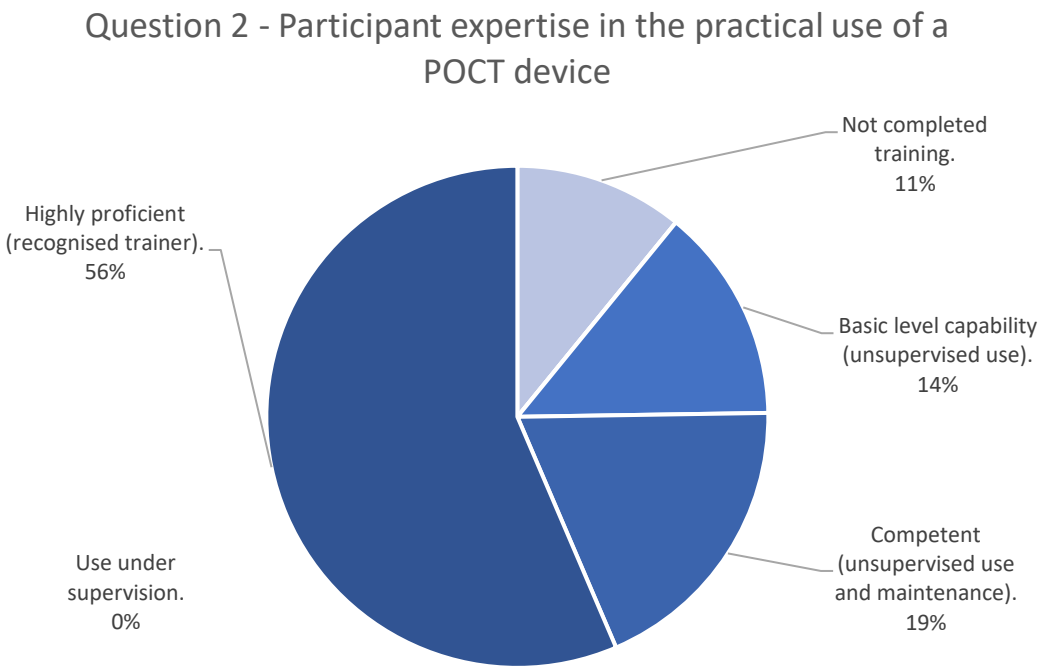

Figure 6.1 - Areas of clinical expertise as a function of POCT use by study participants (n=101).

Figure 6.2 gives an overview of the types of POCT used in participant's area of practice. Mimicking the findings of Chapters 4 and 5 in this regard, blood gas and blood glucose were again found to be most prevalent, being indicated by 77% and 76% of respondents respectively. A further 2 types of test were also found noted by more than half of the study sample; blood coagulation tests (63%) and urine pregnancy / urinalysis (52%).

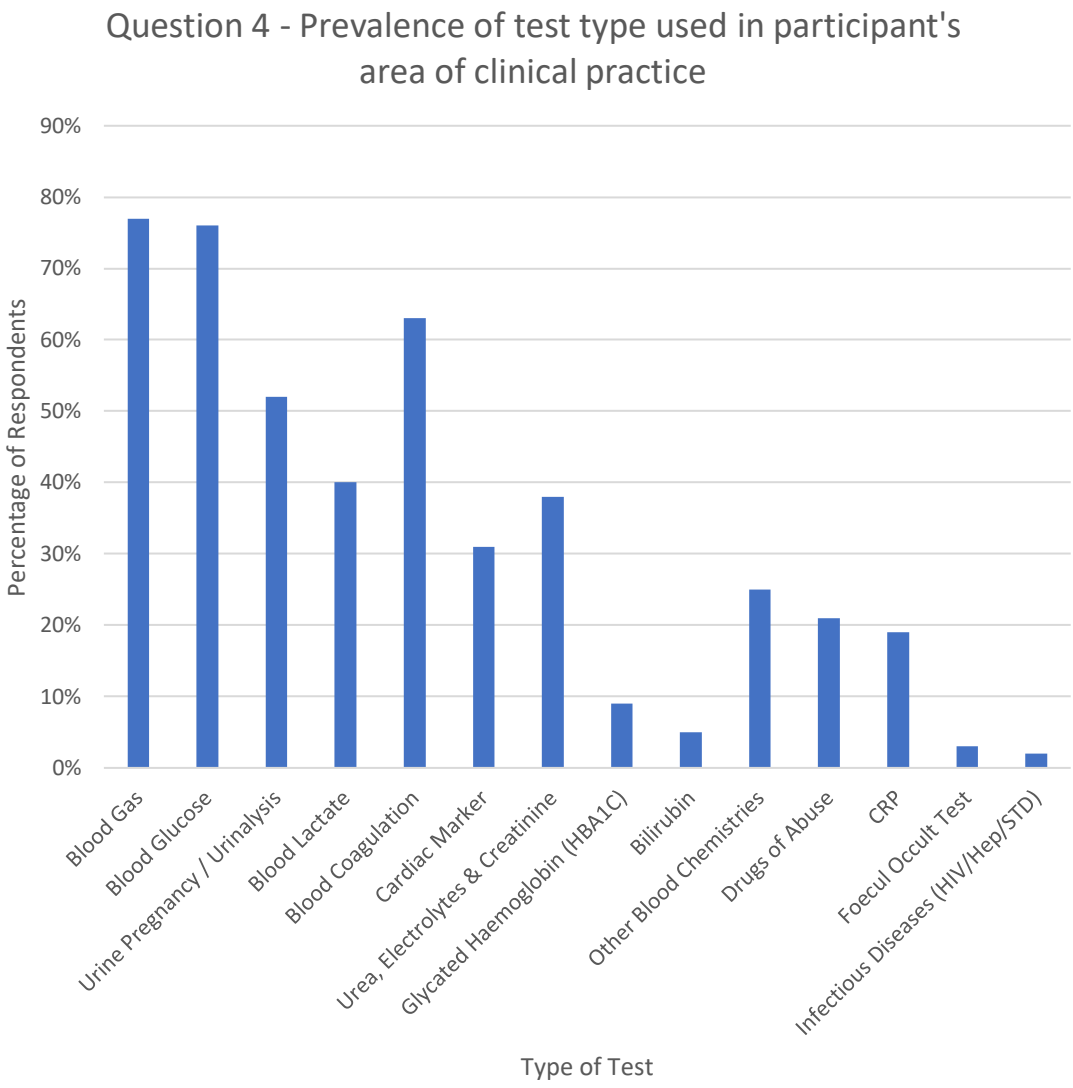

Figure 6.2 - Most common POCT devices used in areas of clinical practice with respect to percentage of respondents for each (n=101).

6.3.1 Economic Issues

Despite the possible expectation that issues concerning quality assurance of testing and associated results when utilising POCT would be most important to those within the clinical biosciences group, it was the economics of testing that was the most prevalent issue with 90 of the 101 participants agreeing that POCT is more expensive than CLT on a cost per test basis, as illustrated in Figure 6.3.

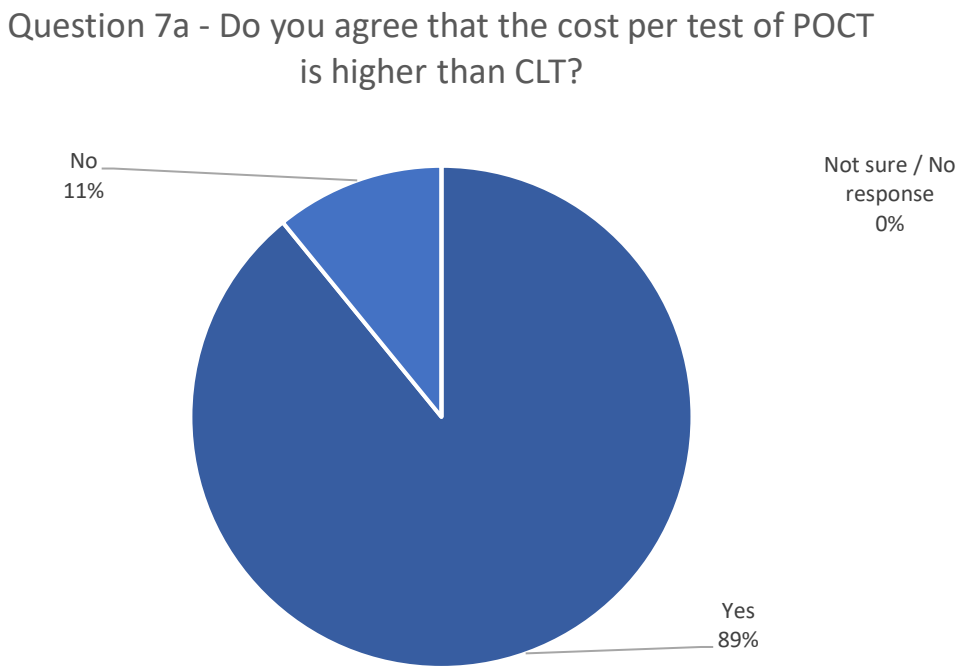

Figure 6.3 - Response of clinical bioscientists to POCT cost per test in comparison to CLT (n=101).

The study sample was more of the opinion that POCT provides longer term benefits than not, such as reduced hospital length of stay and a reduced number of outpatient appointments, with 22% of the sample "strongly agreeing" and a further 30% "agreeing", as shown in Figure 6.4. 30% of the clinical bioscientists here gave a "neutral" response with an answer of 5-6 on the 10-point scale used. Only 9% "disagreed" with this, with a further 9% "strongly disagreeing".

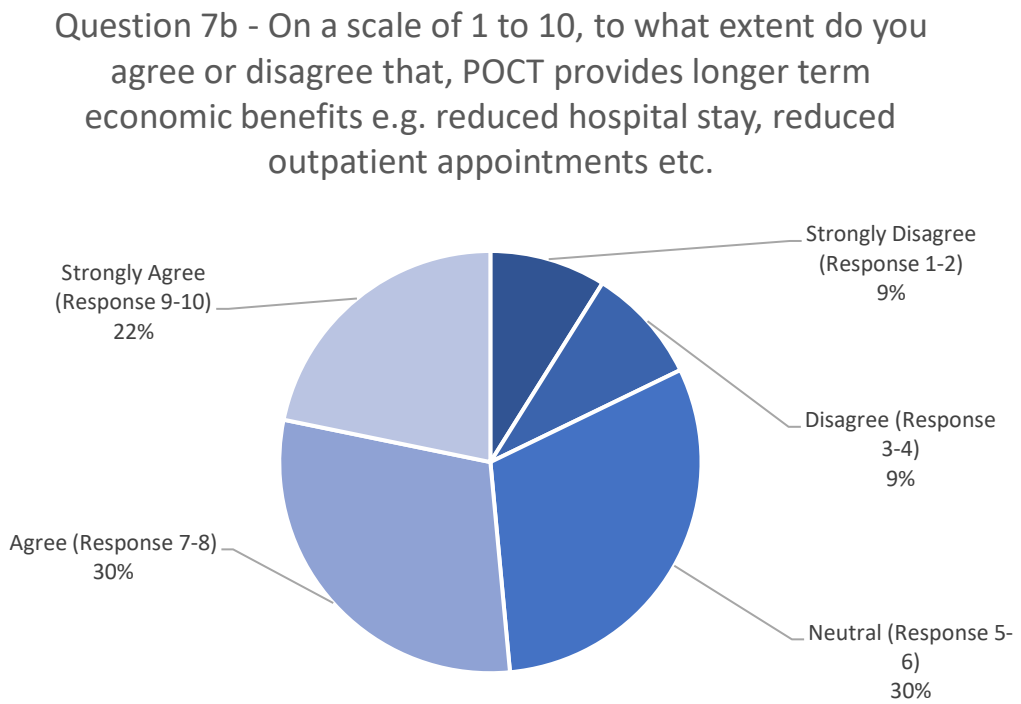

Figure 6.4 – Clinical bioscientists opinion on the longer term economic benefits attainable through the use of POCT (n=101).

Respondents “disagreeing” or “strongly disagreeing” that POCT provides longer term economic benefits were questioned as to why they though such potential benefits were not being realised, with responses as follows:

- *“POCT is misused as an argument. Better logistics can often solve the problem. Although, there are sometimes better outcomes because POCT is [much quicker than] the whole procedure of taking blood and sending to [the] central lab.”*
- *“Lab investigations are also very fast.”*
- *“Usually need additional non-POCT test results to treat/diagnose patient.”*
- *“Accuracy of the analysers and provider/physician mistrust. Also cost.”*
- *“Due to lack of skill/trust in results by ward operators most tests are duplicated in the main lab for confirmation. Also, there is high risk of unsuitable samples creating incorrect results, e.g. haemolysed blood gas samples giving falsely high potassiums, so unusual results are repeated in main lab. This means many of the time benefits associated with POCT are not realised in practice.”*
- *“Length of stay not closely linked to TAT for laboratory tests performed by POCT.”*
- *“Do not think that in a hospital setup there are long term economic benefits.”*
- *“Poor quality systems.”*
- *“The LOS [length of stay] at the emergency [department] does not really depend on the result of the POCT as often other procedures have to be done. Also, the admission may take some time depending on bed availability.”*
- *“The rationality for using POCT is not linked to economic benefits.”*
- *“Instrument complexity.”*
- *“The benefits of early diagnosis and treatment are not quantified as a cost/benefit. Whereas, the costs of POCT are evident to all managers, in remote sites the reduced need for ambulance transfer is not stated back to POCT.”*

Notably however, as illustrated in Figure 6.5, 71% of the respondents in this study indicated that overall, they saw POCT as being a cost-effective system and one that made appropriate use of the increased expense incurred.

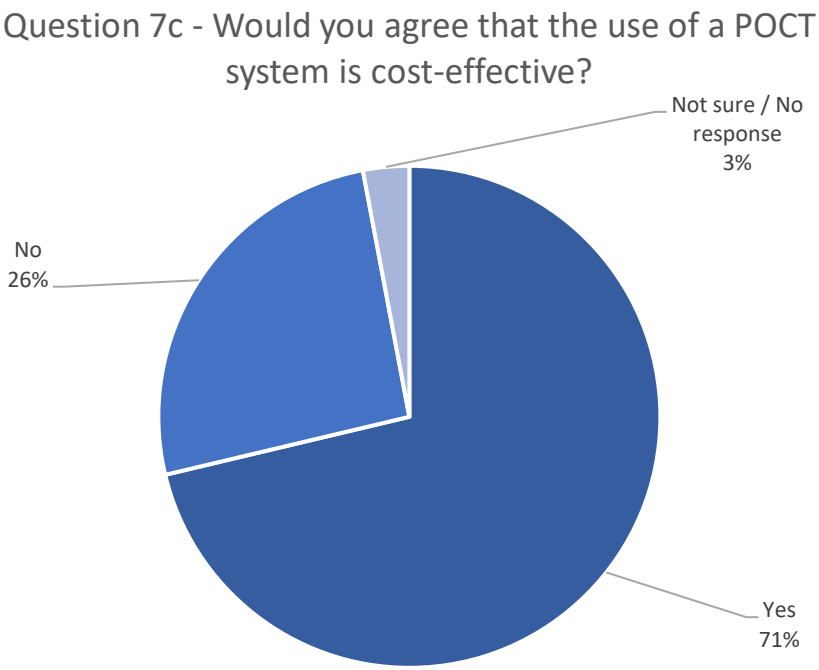

Figure 6.5 – Response of clinical bioscientists to the cost-effectiveness of POCT systems (n=98).

As was found in the previous studies (Chapters 4 and 5), clinical opinion on procurement, reimbursement and budgeting with respect to the interdepartmental nature of devices was found to be significantly varied, as indicated by Figure 6.6. Notably, of the 38 respondents who "disagreed" or "strongly disagreed" that these aspects sufficiently accommodated the interdepartmental nature of POCT in their institution, 27 indicated that this made it more difficult to utilise POCT to its full potential in their place of work.

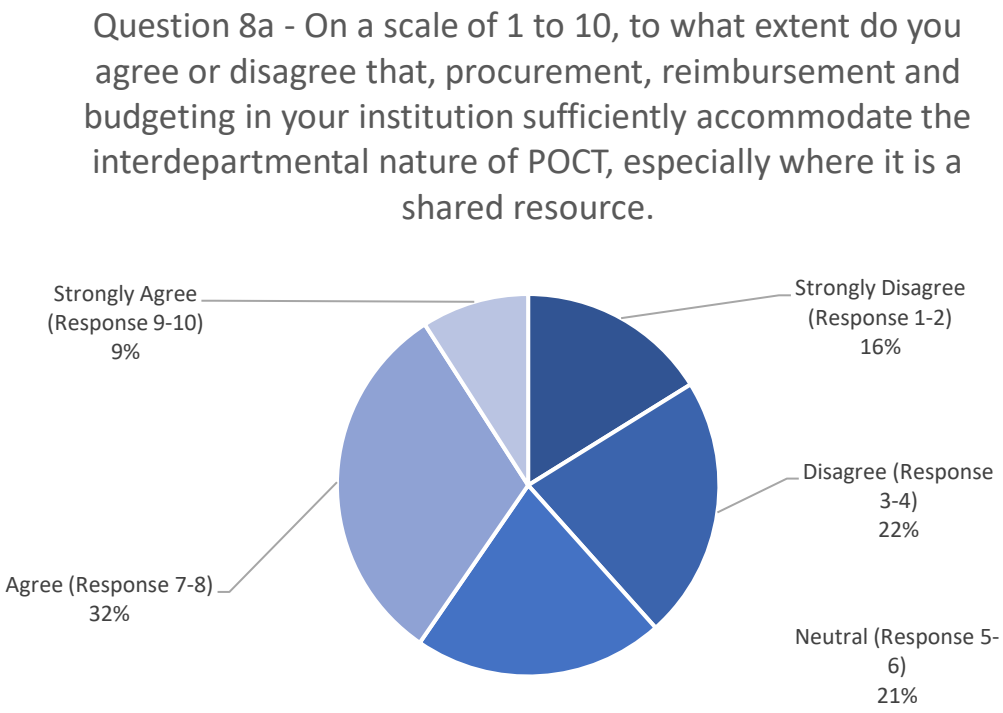

Figure 6.6 – Clinical bioscientists opinion on procurement, reimbursement and budgeting for POCT with respect to the interdepartmental availability of such devices (n=99).

The relevance of specific economic issues in regard to how this opinion is arrived at was also considered. The respective issues include; difficulties in justifying the use of POCT due to the higher cost per test in comparison to traditional testing methods; difficulties in justifying the implementation of a POCT system due to unclear cost-effectiveness and complexities in comparing to traditional methods of testing; difficulties in justifying the implementation of a POCT system due to high initial outlay costs; issues with regard to budget contributions due to the "silo" nature of separate departmental budgeting, and; difficulties in obtaining reimbursement for POCT. The distributions of responses received are shown in Figure 6.7 and it is interesting to note that the "not relevant" response category is the least frequently stated across all parts, with the "sometimes", "fairly" or "very relevant" responses found to be most often used. It is therefore apparent from these results that clinical biosciences cohort is very much of the opinion that these particular economic issues, as identified within the relevant literature base, are the most relevant to their profession.

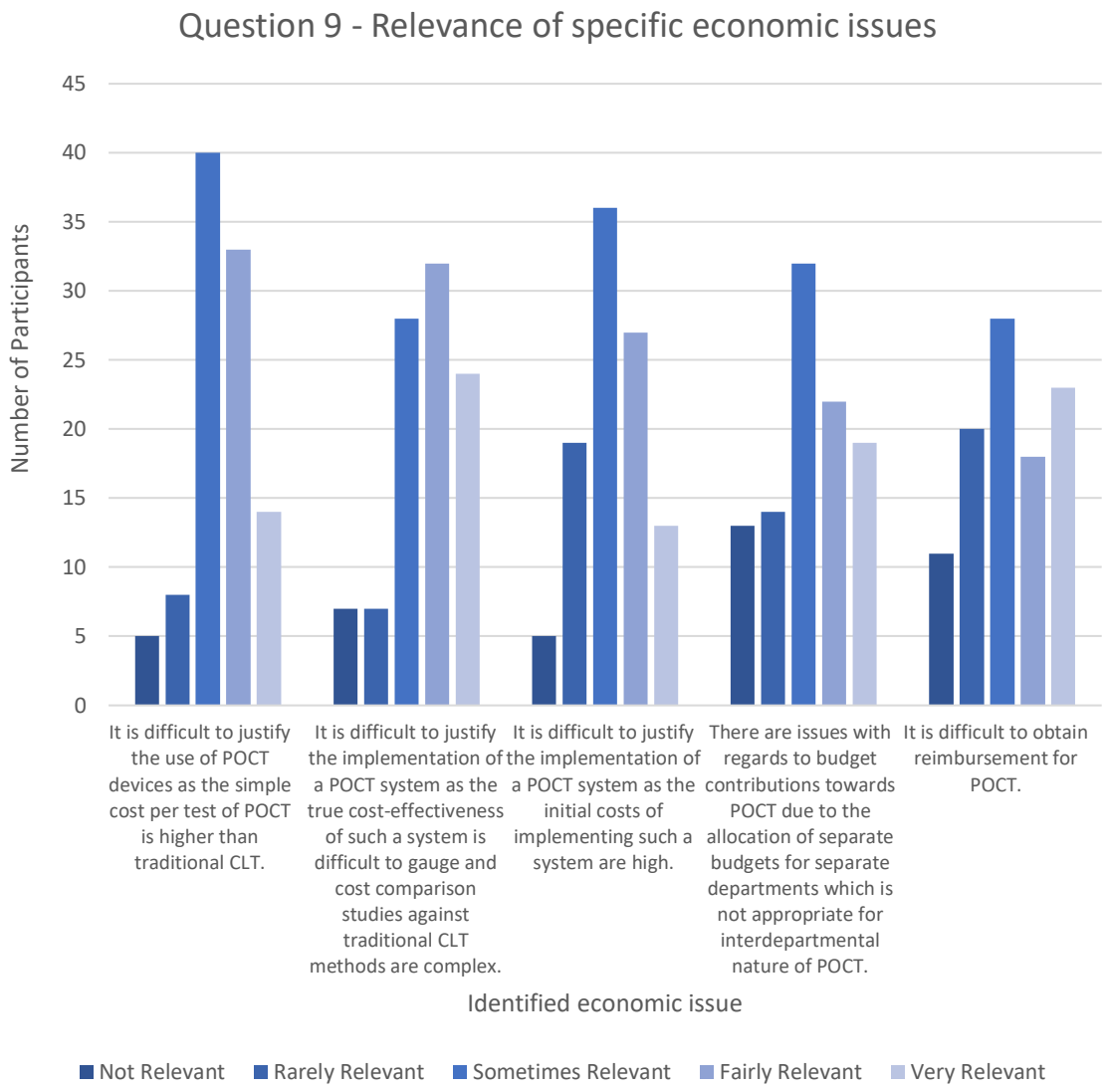

Figure 6.7 – Response of clinical bioscientists to the relevance of specific economic issues prevalent within their own work practice (n=101).

6.3.2 Quality Assurance & Regulatory Issues

The initial focus for the consideration of quality assurance and regulatory issues was with respect to the dispersed nature of POCT devices leading to errors caused by untrained or non-competent staff using the devices. As illustrated in Figure 6.8, the opinion of these participants showed very strong agreement with this proposition, with 46% of the group "strongly agreeing" and with a further 28% "agreeing" with this sentiment. Only a small proportion of the clinicians either "strongly disagreed" (8%) or "disagreed" (6%) that this was the case.

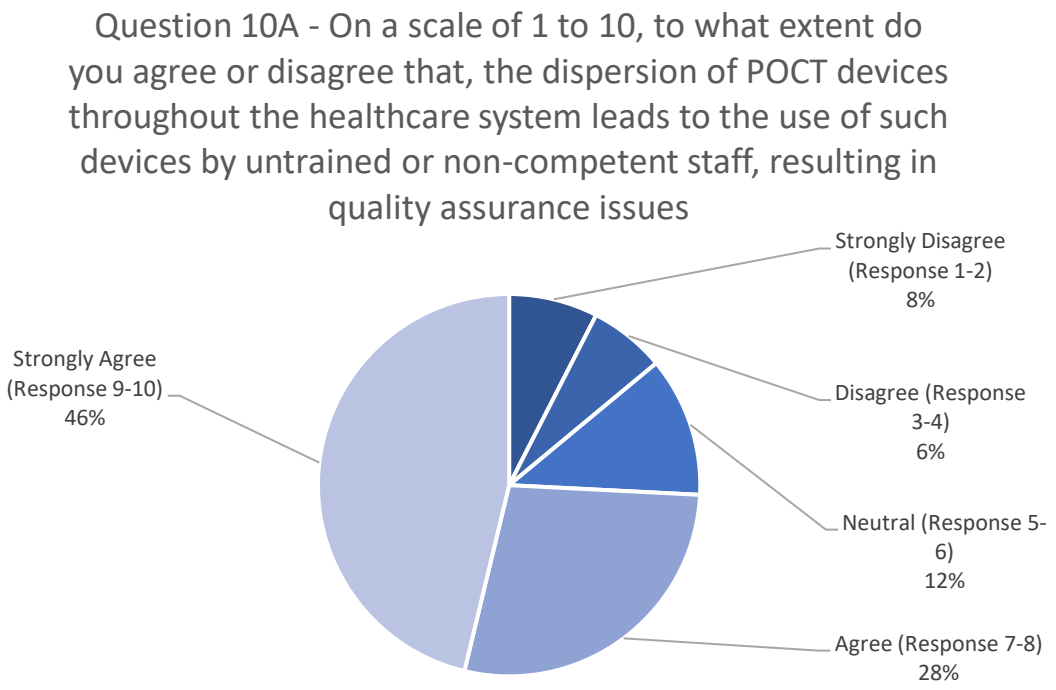

Figure 6.8 – Response of clinical bioscientists to how the dispersed nature of POCT devices leads to use by untrained or non-competent staff, resulting in quality assurance issues (n=93).

Of the 69 respondents "agreeing" or "strongly agreeing" here, 37 indicated that this made it more difficult to attain a timely and reliable diagnosis in comparison to CLT, 22 indicated that it did not make it more difficult, and 10 did not offer a response.

Regulatory compliance has been found to be an area of significant debate throughout the research outcomes reported thus far. Much like the previous studies carried out, significant variation in opinion was found with respect to the complexity of regulations for analytical testing accreditation here, as noted in Figure 6.9. 15% of the sample group "strongly disagreed" that regulations were overly complex, while 13% "disagreed". 25% of responses were "neutral" in terms of their position on the 10-point scale, while 29% of participants "agreed" an a further 18% "strongly agreed" with the question statement.

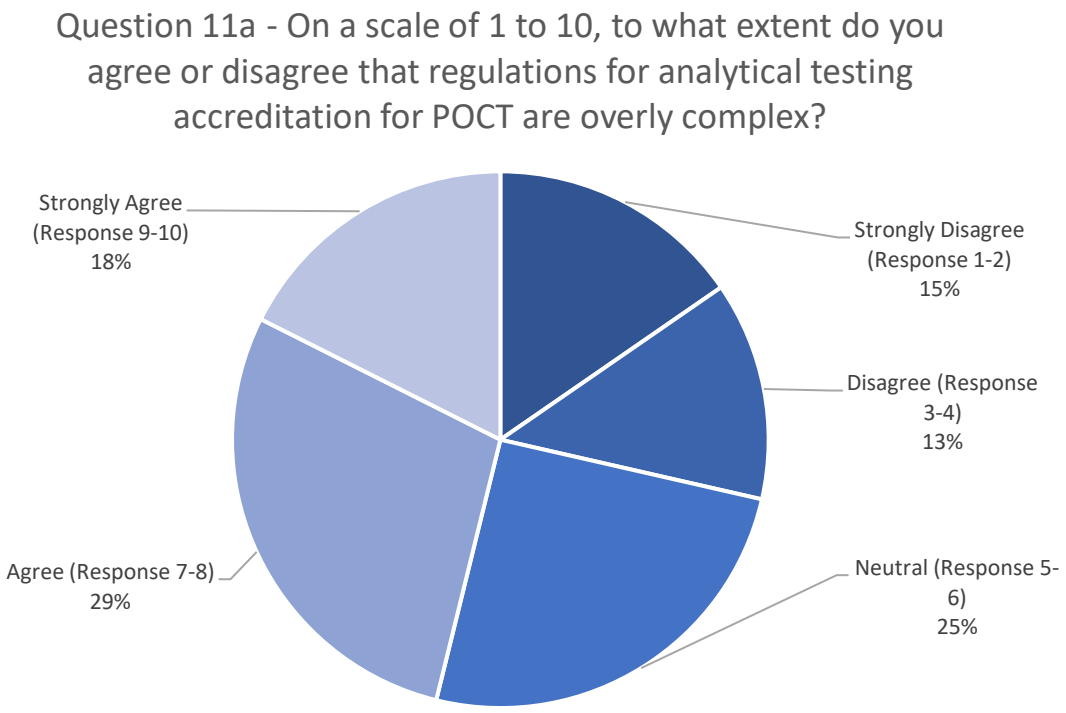

Figure 6.9 – Clinical bioscientists opinion on the complexity of the regulatory requirements and accreditation for analytical testing using POCT devices (n=91).

Of the 42 responders either "agreeing" or "strongly agreeing" that the regulations are overly complex, 25 indicated that this made it more difficult to attain a timely and reliable diagnosis in comparison to CLT, while 11 said that it did not make it more difficult. 6 participants failed to give a response to this question.

With respect to the level of training and support provided by the central laboratory service in regard to attaining the necessary compliance, perhaps not surprisingly, the clinical sciences study group here was of a significantly strong opinion that levels of support are excellent, with 42% of participants indicating a "very high" response and another 32% of individuals indicating a response of a "high". The overall response distribution can be seen in detail in Figure 6.10.

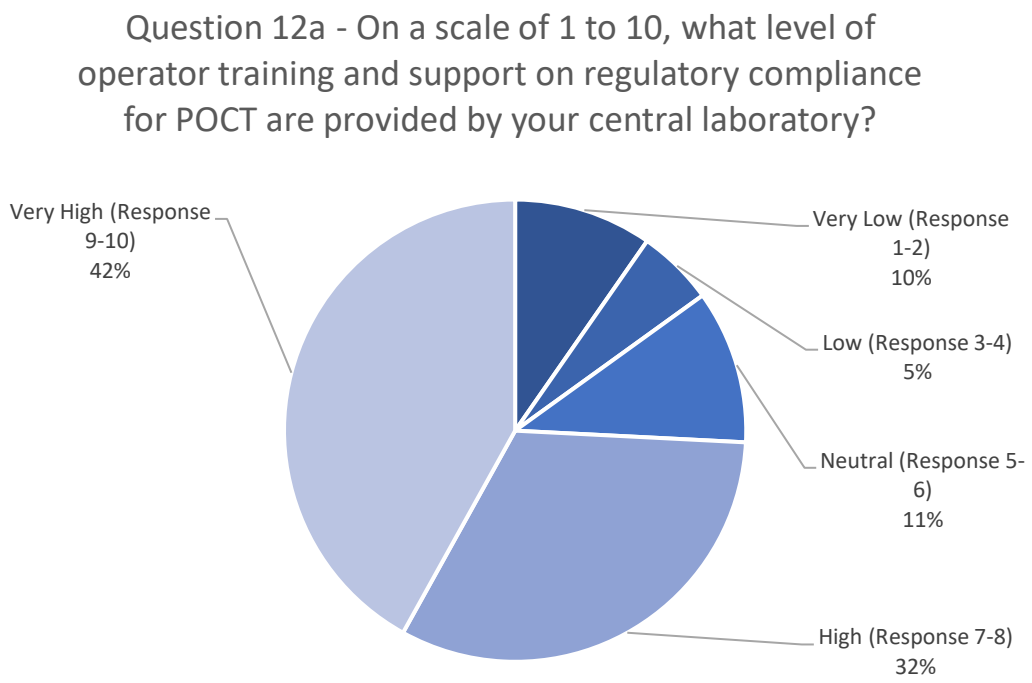

Figure 6.10 – Response of clinical bioscientists to the level of operator training and support on regulatory compliance for POCT provided by the central laboratory service (n=93).

Of the 14 clinical bioscientists who indicated levels of training as being "low" or "very low", 11 believed this made it more difficult to make a timely and reliable diagnosis in comparison to CLT, while 3 believed it did not make it more difficult.

As seen previously in the analyses of the data from the UK and USA studies, the perceived relevance of the same issues here was found to be pertinent with respect to this category of barrier to adoption of POCT, namely; errors caused by incorrect quality assurance procedures by untrained/non-competent staff operating the devices; issues caused by non-laboratory operators of devices due to regulations written for traditional laboratory equipment being inappropriately applied to POCT; issues with maintaining regulatory compliance due to a number of changes in the relevant regulations; issues with maintaining regulatory compliance due to the dispersed nature of POCT, and a lack of improvement of POCT devices caused by product approval hurdles that discourage economic investment in their development. As illustrated in Figure 6.11, all of these issues were found to be of some importance for the clinical biosciences cohort, with "sometimes relevant" and "fairly relevant" found in general to be the most popular response categories. An exception here is with respect to the issue regarding a lack of development of POCT devices caused by product approval hurdles discouraging economic investment in their development. Unlike previously, this specific issue was the one area in which "not relevant" was not the least frequent response category and, although "sometimes relevant" was the most frequent response, "rarely relevant" was the second most

frequent, indicating a general trend towards this being of lower relevance when considered by clinical biosciences only in comparison to the other specific issues identified within this category of barrier to adoption.

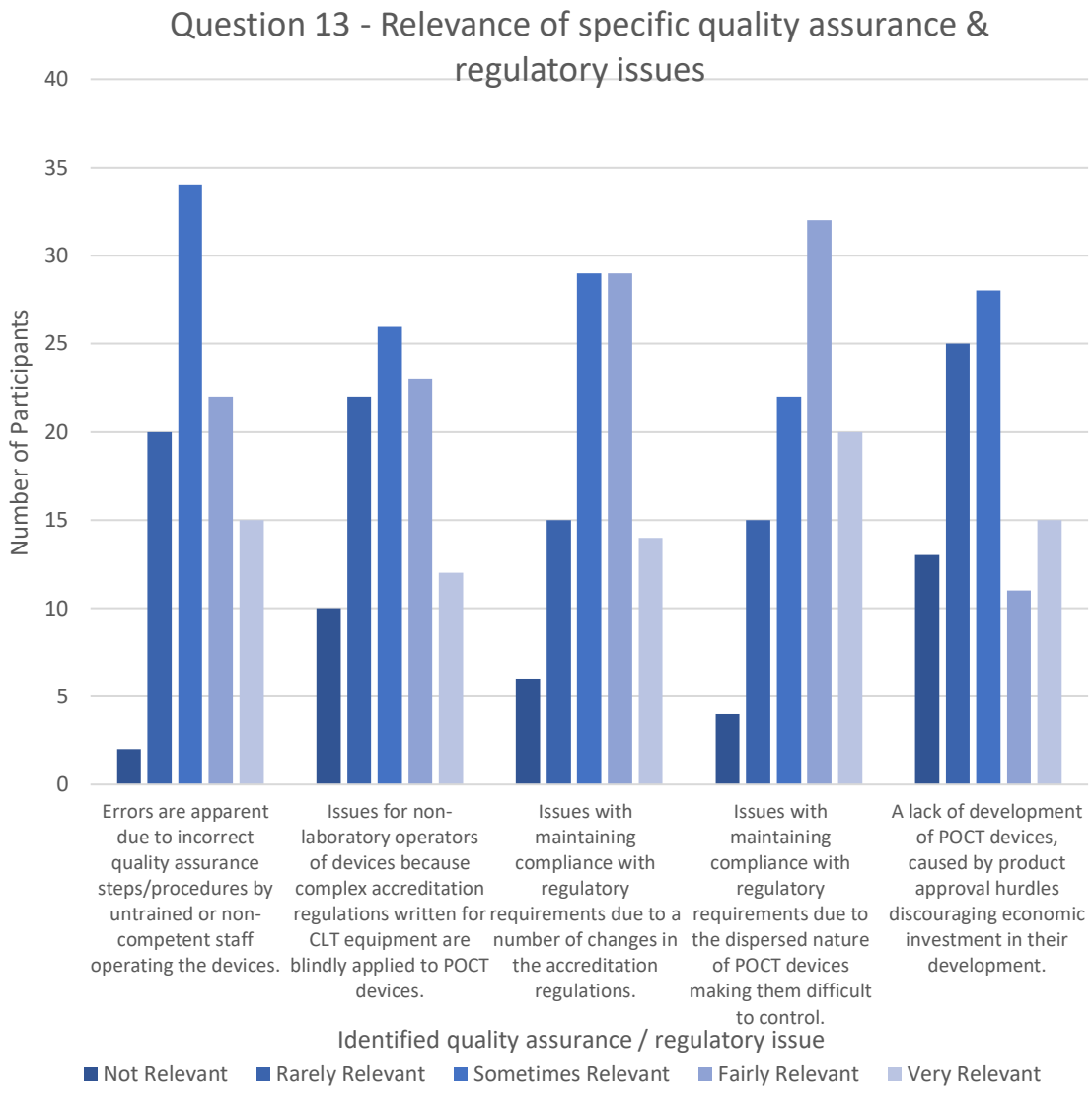

Figure 6.11 – Response from clinical bioscientists on the relevance of specific quality assurance and regulatory issues within their own area of professional practice (n=93).

6.3.3 Device Performance & Data Management Issues

As clinical bioscientists are most aligned with the central laboratory service in professional practice, opinion was gauged with respect to their views on the analytical performance of POCT devices in comparison to CLT instruments. This study found that 44% of participants indicated that the level of analytical performance of POCT devices was "high" in comparison to CLT, 22% indicated a "neutral" level of performance and a further 21% considered the analytical performance of POCT to be at a "lower" level in comparison to POCT. The full results are indicated in Figure 6.12. Only a small proportion of the study group were aligned with either end of the response scale with, with 9% and 4% indicating "very high" or "very low" levels of

performance, respectively. OF the 23 participants who indicated analytical performance as being “low” or “very low”, 16 believed this makes it more difficult to attain a timely and reliable diagnosis in comparison to CLT, while 7 did not believe it makes it more difficult.

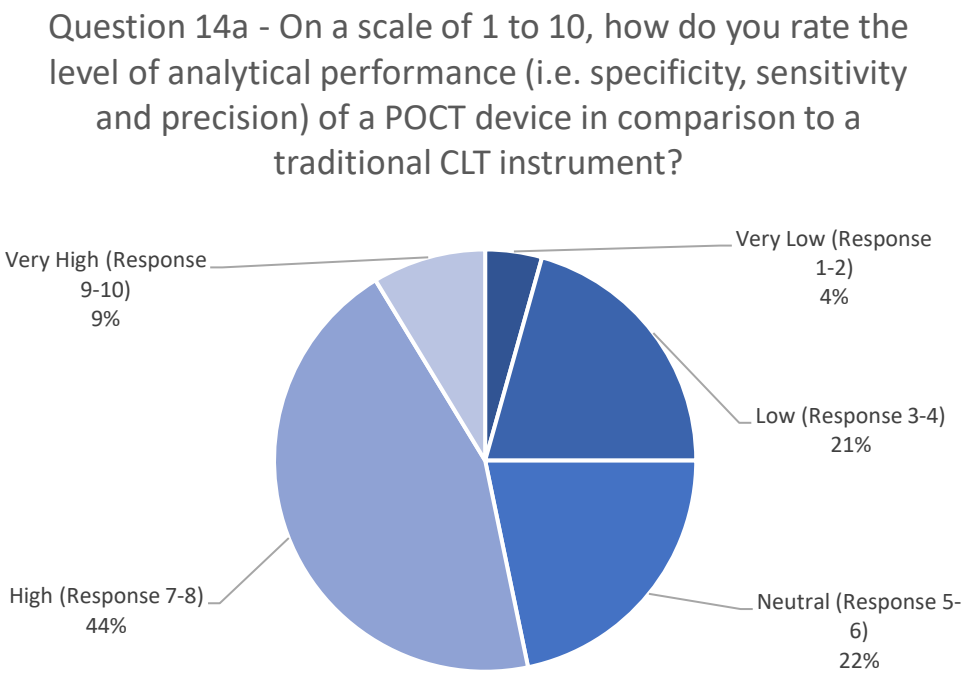

Figure 6.12 – Response of clinical bioscientists on the level of analytic performance of POCT devices (n=92).

As in the previous studies, the sample group were questioned with regards to the connectivity of POCT devices in comparison to CLT, with results in Figure 6.13. Opinion was significantly varied here; 21% indicating connectivity to be “very good”, 26% as “good”, 23% as “neutral”, 14% as “poor” and 16% as “very poor”. Of the 27 respondents indicating connectivity as “poor” or “very poor”, a large majority of 24 believed that this made it more difficult to attain a timely and reliable diagnosis in comparison to POCT.

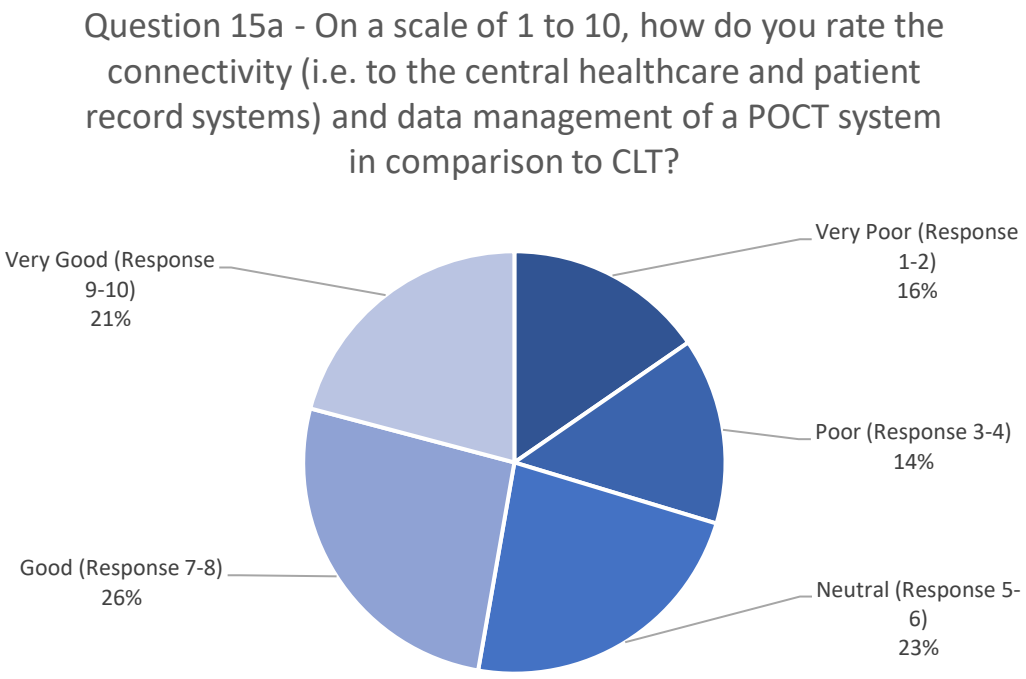

Figure 6.13 – Clinical bioscientists opinion on the connectivity and data management capabilities of a POCT system (n=91).

Clinicians in this study, in general, indicated that POCT devices are not difficult to use, as illustrated in Figure 6.14. The largest frequency of response here was to indicate that POCT devices are "very easy" to use, with 44% of the clinical bioscientists here indicating this to be the case. A further 31% indicated their use to be "easy", while 14% were of "neutral" opinion and 9% found POCT devices "difficult" to operate. Just 2% of the response indicated that POCT devices were "very difficult" to utilise in comparison to CLT. Of the 10 participants believing the use of POCT to either be "difficult" or "very difficult", 3 indicated this made it more difficult to make a timely and reliable diagnosis in comparison to CLT, while 4 thought this did not make it more difficult. 3 responders here failed to give a response. These 10 respondents were also invited to make suggestions as to how the usability of POCT devices could be improved, with responses as follows:

- *"It's idealistic to compare each and every POCT device with the quality testing of laboratory instrumentation, however, POCT devices, having internal calibration mechanisms, quality control shut off points and reporting (all results directly) to clinicians would be ideal."*
- *"Suffice to say that if more than 1 POCT device has to be used for testing on a patient, the efficiency goes way down; i.e. TAT may be no better than CLT and the labour involvement of the caregivers becomes prohibitively large."*
- *"Greater connectivity, greater sensitivity and specificity of the devices/kits."*

- *"1) Better analytical performance (e.g. troponin, the poor performance at low concentrations is why we won't allow it, despite multiple requests by our emergency department). 2) Automatic checks for pre-analytical interferences such as haemolysis. 3) Less false advertising from manufacturers as to POCT's capabilities. 4) Smarter systems, e.g. alarming when the wrong barcode is scanned."*

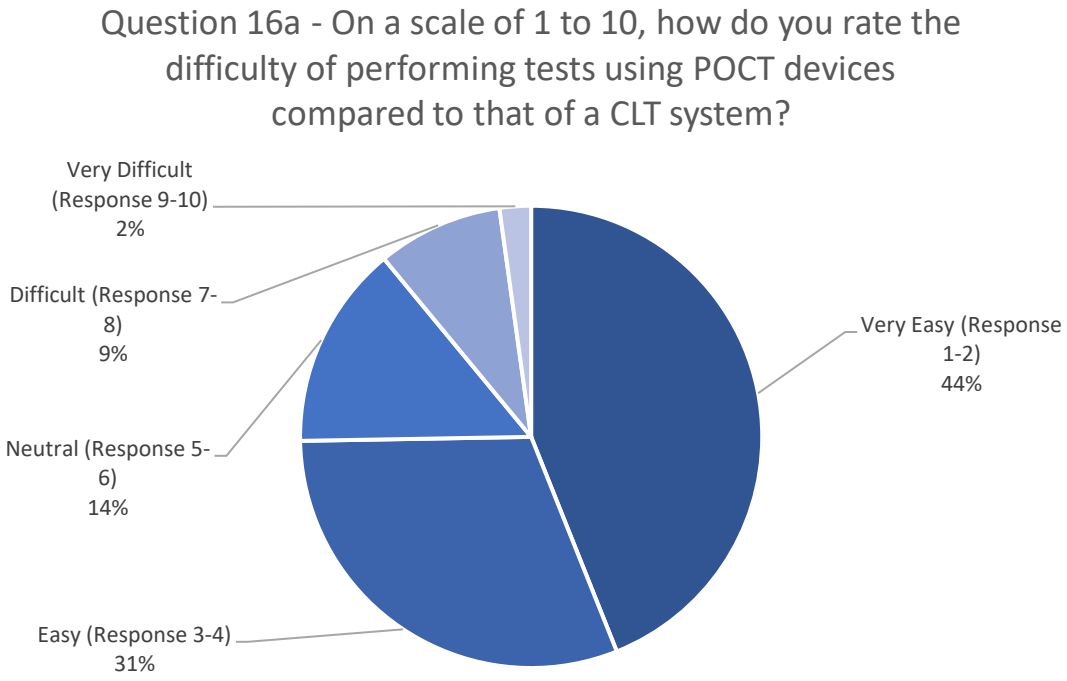

Figure 6.14 – Clinical bioscientists opinion on the degree of difficulty associated with performing tests using POCT devices (n=91).

Whereas, the majority of the findings on data management issues from this part of the study compare to those from the previous UK and USA elements, there are some interesting findings with respect to the relevance of specific issues namely; POCT devices producing reduced analytical performance in comparison to Central Laboratory Testing (CLT); data management issues resulting from poor connectivity between the POCT system and patient record systems, and; operators encountering difficulties with the use of POCT devices. As indicated in Figure 6.15, the most frequent response from the clinical biosciences group for the issues relating to reduced analytical performance and usability difficulties, were "sometimes relevant", while the remaining issue, that regarding problems with data management due to poor connectivity was found to be "very relevant" to a significant number of participants (32 of 101). Across all 3 of the specific issues concerned, "not relevant" area of response was found to be the least frequently indicated, with only 2, 3 and 1 participant indicating this response, respectively.

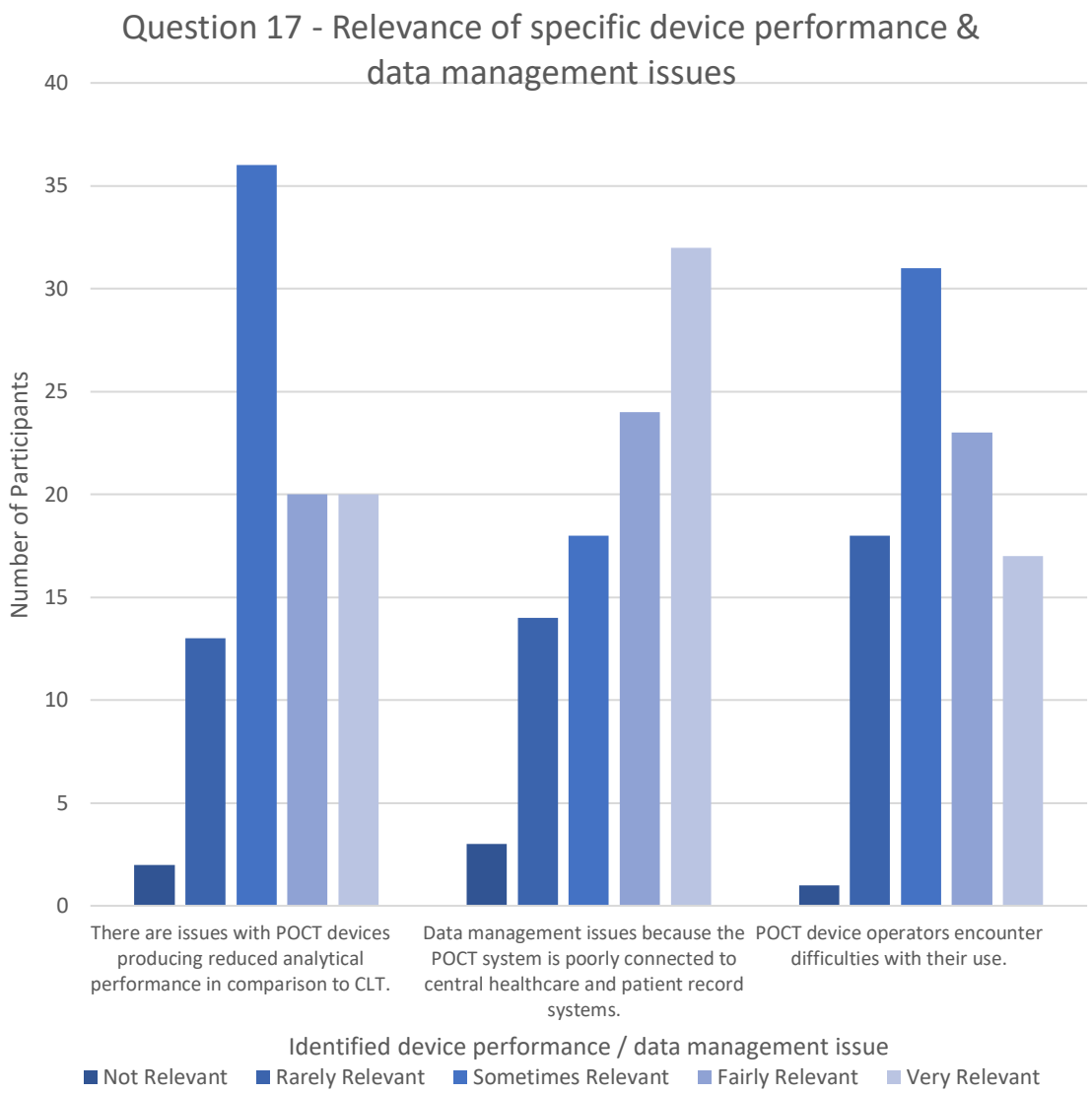

Figure 6.15 – Response of clinician bioscientists on relevance of specific device performance and data management issues within their professional practice (n=91).

6.3.4 Staff & Operational Issues

In terms of how staff and operational issues may act as barriers to the adoption of POCT, as highlighted by a systematic review of the relevant academic literature, this part of study showed several interesting findings. Firstly, the opinion of the clinical bioscientists with regard to the impact of POCT utilisation on the workload of front line clinical staff indicated that 50% of participants were either “agree” or “strongly agree” that there was a significant increase in workload as a result of POCT use. A further 20% of response was “neutral”, while 19% “disagreed” and the remaining 11% “strongly disagreed” that this was the case. The results are shown in detail in Figure 6.16. Of the 46 respondents indicating that they “agreed” or “strongly agreed”, 28 suggested that this reduced staff satisfaction levels in comparison to when utilising CLT, while 16 of the group did not think this was the case. 2 respondents here failed to give a response.

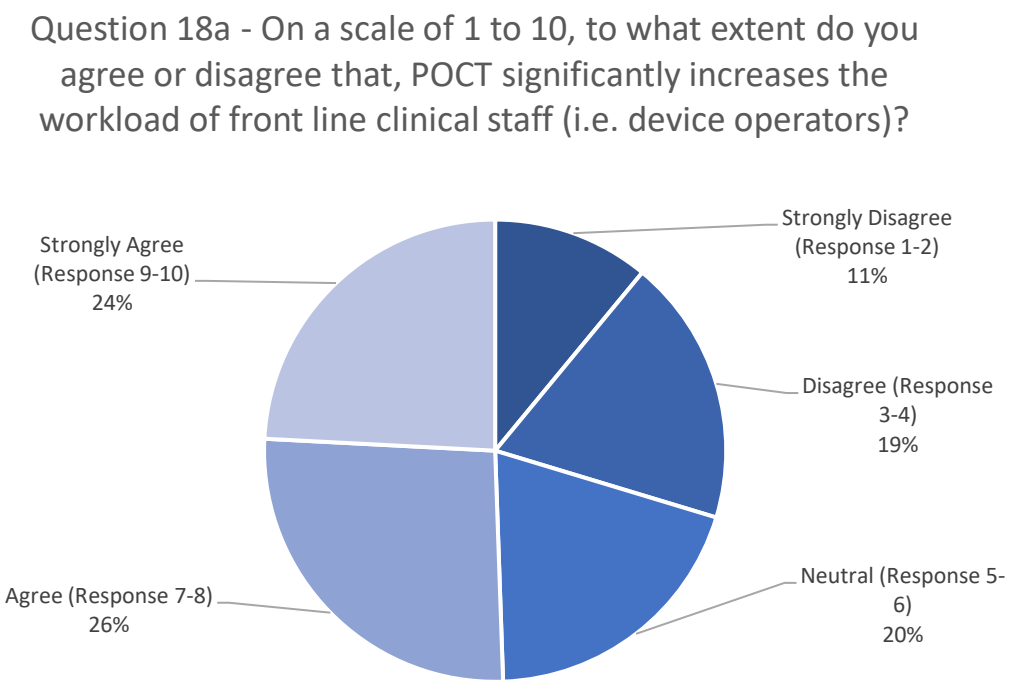

Figure 6.16 – Response of clinical bioscientists of the impact of POCT upon the workload of device operators (n=91).

The sample group were questioned on whether they believed that the central laboratory is reluctant to allow the control of diagnostic testing to be passed on, with results shown in Figure 6.17. Response demonstrated significant variation across the framed categories; 17% as "strongly agree", 24% as "agree", 26% as "neutral", 15% as "disagree" and 18% as "strongly disagree". The 37 respondents "agreeing" or "strongly agreeing" that the central laboratory was reluctant to allow the control of testing to be passed on were questioned as to whether they believed this acted as an impediment to the more widespread uptake of POCT. 20 believed this to be the case and 13 did not think this acted as an impediment, with 4 failing to give a response.

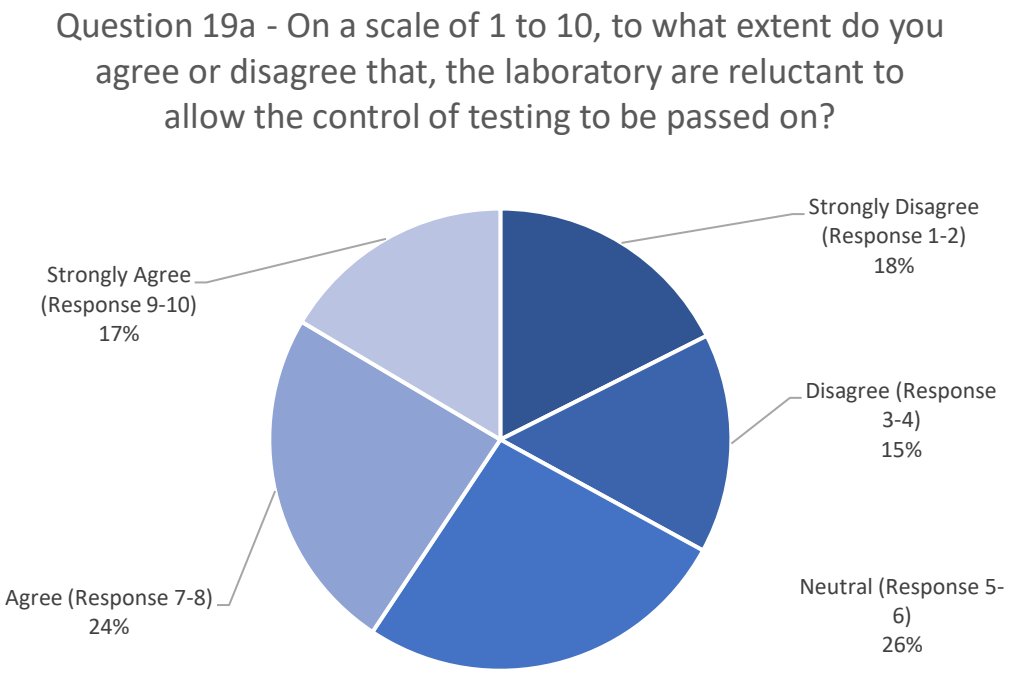

Figure 6.17 – Clinical bioscientists opinion on the reluctance of the central laboratory to release the control of POCT testing to the clinic (n=91).

Figure 6.18 illustrates the response profile of opinion when the respondents were questioned as to whether they believed the clinical care pathway and role of the central laboratory had been altered sufficiently to incorporate the use of POCT, with few responses "disagreeing" (10%) or "strongly disagreeing" (7%) that this was the case. A significant proportion (34%) of the study sample were of a neutral opinion, while 31% "agreed" and 18% "strongly agreed" that sufficient alteration had been carried out. Of the 15 clinical bioscientists that "disagreed" or "strongly disagreed", 10 believed that this makes it more difficult to attain a timely and reliable diagnosis in comparison to CLT, 2 believed it does not make it more difficult, and 3 failed to give a response.

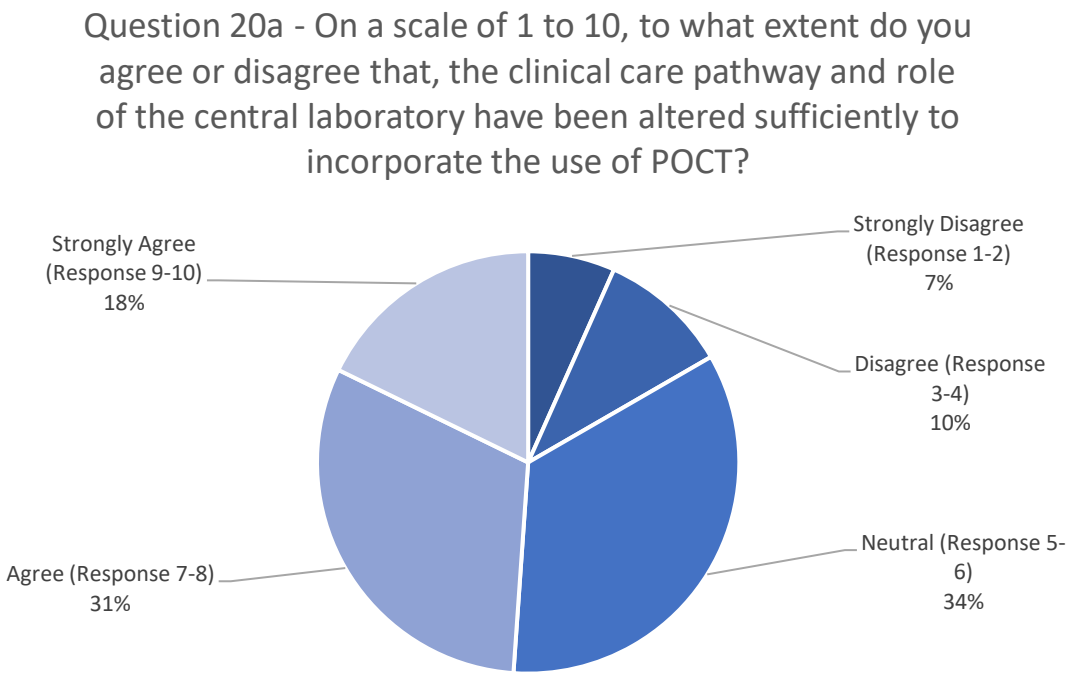

Figure 6.18 – Clinical bioscientists opinion of how the clinical care pathway and role of the central laboratory have been altered to incorporate the use of POCT (n=90).

Consideration of the relevance of the specific issues also yielded findings of interest. These issues relate to the following issues; reduced staff satisfaction levels and increased friction between clinical staff groups due to the use of POCT; impeded uptake of POCT caused by the reluctance of the central laboratory service to release the control of diagnostic testing; inappropriate use of POCT, including over-use and reliance on test results; benefits of POCT being negated due to a requirement for clinical care pathways and role of the central lab to be altered sufficiently; POCT system running inefficiently due to the requirement for an interdepartmental management structure with clear clinical governance for POCT, and; difficulties implementing POCT due to a reluctance to change within healthcare bodies along with a lack of evidence justifying POCT. As shown in Figure 6.19, the “not relevant” response area was found to be very low for the perceived relevance of other categories of impediment, being the least frequent response across all 6 issues investigated here. The inappropriate use of POCT was found to be the most frequent response here, with “fairly relevant” and “very relevant” found to the most popular responses. The most frequent response in all 5 categories of specific interest was found to be “sometimes relevant”.

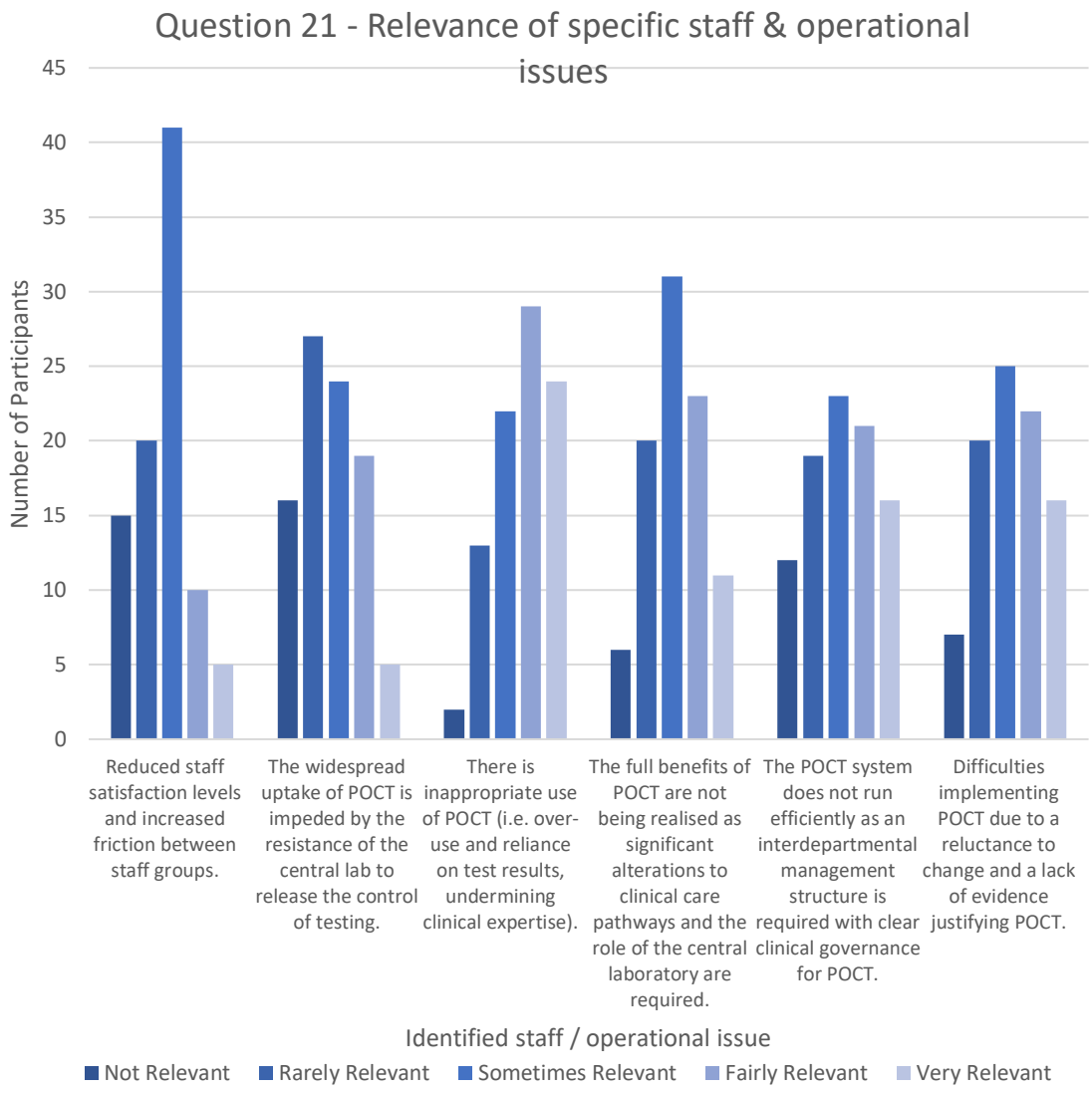

Figure 6.19 – Response from clinical bioscientists of relevance of specific staff and operational issues within their own clinical institution (n=91).

6.3.5 Other General Issues

As this investigation was carried out entirely through an online survey tool, no face-to-face interviews were carried out. The additional information obtained directly from the face-to-face interviews presented in Chapters 4 and 5 were found to be extremely important for attaining insight into participant response and, in many cases, offered clarification of reasons for such responses. The final section of the remote survey tool employed here, as before, incorporates a free-response section related to the core questions, providing an avenue for clinical bioscientists to provide added value to their responses. Participants were firstly asked to give their opinion on the main advantages of POCT in comparison to CLT, with the most frequent responses attained as follows:

- Rapid TAT results in a quicker decision/diagnosis and earlier clinical intervention (73% of respondents).

- Improved patient/operator satisfaction and convenience (including lower blood sample volumes, patient education and buy-in/responsibility) (21% of respondents).
- More efficient patient management (10% of respondents).
- Avoids sample transfer where no laboratory on site or within close proximity (4% of respondents).
- Overcome problems of bad access to hospital/medical care (4% of respondents).
- Offers improved quality of care and better patient outcomes (3% of respondents).
- Reduces risk of sample mix up and simpler sampling process (3% of respondents).
- Improved sensitivity/accuracy (3% of respondents).
- Avoids sample instability issues during transport (2% of respondents).
- Cost savings (including patient education and staff taking pathology call-backs) (2% of respondents).
- Ease of use (2% of respondents).
- Less reliance on a chain of services where delays are more likely with POCT devices (individual response).
- POCT devices take up a low amount of space (individual response).
- Improves direct communication between patient and doctor (individual response).
- Offers increased user control of testing/treatment (individual response).

Similarly, study participants were asked about the main disadvantages of POCT in comparison to CLT. The most frequent responses here include:

- Poor quality/inaccuracy of result obtained by untrained or non-competent staff (including user awareness limitations, inexperience of clinical staff etc.) (38% of respondents).
- Increased cost (30% of respondents).
- Reduced accuracy compared to CLT and subsequent lack of confidence in results (17% of respondents).
- Poor connectivity to central healthcare and patient record systems/other ICT issues (13% of respondents)
- Significant amount of staff training required (time, cost & management) (13% of respondents).
- Takes up a lot of staff time to operate (increased workload) (9% of respondents).
- Quality management requires significant resources and is difficult to control due to dispersed nature (9% of respondents).

- Difficulty in ensuring continued staff competency and unfamiliarity caused by a lack of regular use (7% of respondents).
- Physical distance from CLT / experts and troubleshooting help thereby making it difficult to remotely manage (5% of respondents).
- Lack of CLT oversight, dedicated staff or quality programme (3% of respondents).
- Risk of inappropriate use (2% of respondents).
- Reduced test menu in comparison to CLT (2% of respondents).
- Clinical governance unclear (individual response).
- Maintenance of dispersed devices is difficult (individual response).
- POCT is inefficient for handling large test volumes (individual response).
- Lack of outcome study evidence available for POCT (individual response).
- Manufacturers interfering with hospital policies (individual response).
- Poor general usability of devices (individual response).

In order to ascertain where POCT is deemed to be most valuable to clinical bioscientists, participants were also asked which diseases and/or conditions benefited the most through its use. The most frequent responses received are summarised here:

- Diabetes i.e. glucose monitoring (44% of respondents).
- Cardiac conditions (29% of respondents).
- Blood coagulation, i.e. International Normalised Ratio (INR) monitoring (25% of respondents).
- Critical care conditions, i.e. Intensive Care Unit & Emergency Department (25% of respondents).
- Respiratory conditions, i.e. blood gas testing (15% of respondents).
- Pregnancy / Obstetrics / Neonatology (14% of respondents).
- Infectious diseases (7% of respondents).
- Sepsis testing (7% of respondents).
- Other blood tests, e.g. pH, bilirubin, lactate etc. (7% of respondents).
- Surgical procedures (6% of respondents).
- General blood issues, i.e. Blood counts and haemoglobin tests (5% of respondents).
- Deep vein thrombosis (5% of respondents).
- General triage (4% of respondents).
- Electrolytes issues (4% of respondents).
- Urinalysis tests (4% of respondents).
- Renal conditions (4% of respondents).

- Drug abuse patients (3% of respondents).
- Skin conditions (2% of respondents).
- Dehydration (individual response).
- Influenza (individual response).

The most valuable insight here, in terms of achieving a solutions-based approach to the research question, was gained through the study of this groups opinion on how to overcome the impediments that exist in relation to the more widespread uptake and use of POCT within hospital environments. The core opinions and frequency of response attained from clinical bioscientists in this regard are summarised below:

- Audit the use of POCT to provide evidence of clinical and/or economic benefits to stakeholders as a way to overcome issues such as mistrust in its utility and a lack of full backing for its implementation by the healthcare system, including dissuading negative opinions on POCT e.g. competition to the laboratory, etc. (11% of respondents).
- Improve the training processes and periodic competency assessments for all users (10% of respondents).
- Improve the connectivity of POCT devices to central healthcare systems and develop appropriate connectivity regulations (9% of respondents).
- Central laboratory to provide oversight of QA, maintenance and training (8% of respondents).
- Increase the support for POCT via dedicated central laboratory staff to operate the devices (7% of respondents).
- Reduce costs (6% of respondents).
- Improve the analytical performance of devices (6% of respondents).
- Improve/simplify the QA processes (4% of respondents).
- Support close collaboration/communication between the areas of clinical specialism involved in the use of POCT (3% of respondents).
- Offer more tests on fewer devices (3% of respondents).
- Increase buy-in from top management (3% of respondents).
- Improve usability of the devices (2% of respondents).
- Attain better correlation between POCT and central laboratory tests, i.e. regulate the exact parameters/analytes for each test (2% of respondents).
- Increase the test menu available through POCT (2% of respondents).
- Implement a clear POCT policy/strategy (2% of respondents).
- Increase reimbursement based on total costs of healthcare chain involved and not just the test itself (individual response).

- Re-evaluate the "traditional lab" standards of regulation/accreditation and introduce specific POCT regulations (individual response).
- Increase POCT development for infectious diseases (individual response).
- Focus POCT on qualitative tests only (individual response).
- POCT devices should be leased from the manufacturer such that the hospital pays for the test strips it uses (individual response).
- Limit use to where POCT is strictly necessary (individual response).
- Implement "user pays" for POCT, i.e. pays for the convenience (individual response).
- Increase the resources made available to manage POCT (individual response).

In the final part of this survey, clinical opinion was investigated with respect to the relation between the cited categories of impediment and their impact upon the current mode of POCT adoption. The clinical study group here were asked to rank the 4 categories of issue that had been identified from the previous systematic literature review (economic, quality assurance & regulatory, device performance & data management and staff & operational issues) on a scale of 1 to 4, with 1 being most important in regard to POCT uptake and 4 being least. As in previous chapters, the data was managed using a tiered scoring system to accumulate the categories into a final ranking order (4 points for first-place ranking, 3 for second, 2 for third and 1 point for fourth-place). The scoring frequency of the resulting responses are provided in Figure 6.20. As indicated, economic issues received the highest pooled score of 220. This was followed by device performance & data management and quality assurance & regulatory issues with scores of 200 and 196, respectively. Finally, perhaps surprisingly, staff & operational issues received had score of 144 which fell considerably behind the other studied categories.

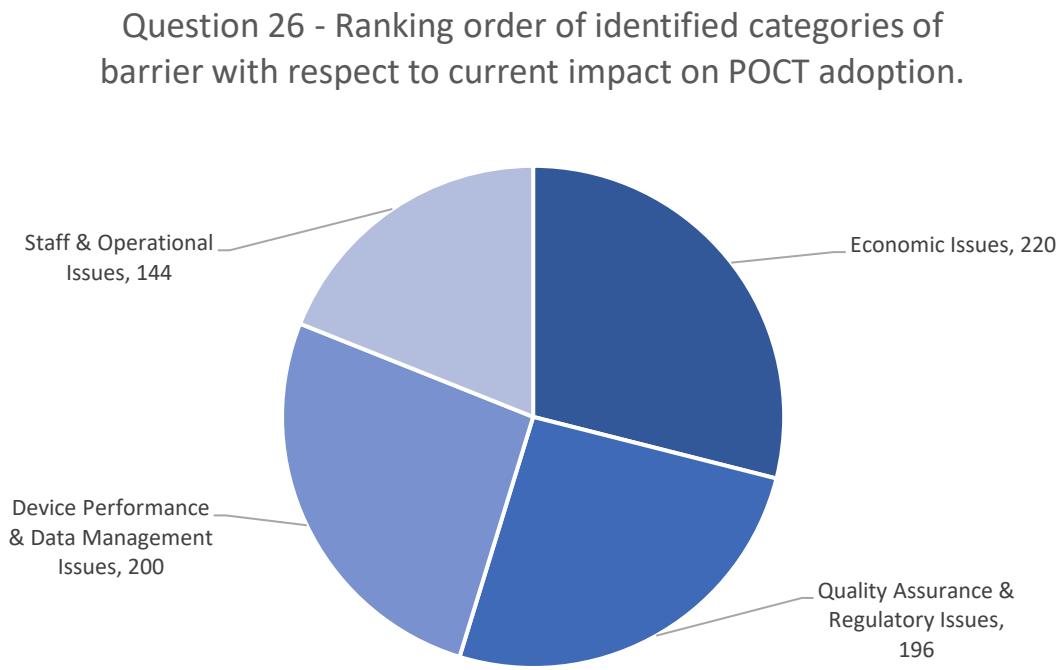

Figure 6.20 - Clinician opinion of clinical bioscientists on the ranking of those categories of barrier to adoption of POCT indicated by the systematic literature review (n=76).

6.4 Discussion

As was the case for the studies conducted amongst a range of UK and US hospital-based clinicians, presented in Chapters 4 and 5, economic issues were deemed to be a significantly important barrier to adoption for POCT by the clinical bioscientists in terms of current impact upon uptake, ranked in first-place here. However, whereas quality assurance and regulatory issues were ranked as being as important as economic issues (in terms of impact on uptake) by UK clinicians, the clinical bioscientists ranked device performance and data management issues as being in second-place, with quality assurance and regulatory issues third. Although, it is recognised that the difference of 4 points in this scoring system employed here is not significant, it can be stated that the clinical biosciences cohort is of the opinion that the category of device performance and data management issues, has at the very least as much an impact on POCT uptake as quality assurance and regulatory issues. It is suggested that the reason for the prevalence of this opinion may centre around the responsibility that clinical bioscientists hold with respect to ensuring that accurate information and guidance is provided to other healthcare professionals regarding the operation of POCT devices. The role of clinical bioscientists is becoming increasingly important with respect to ensuring that the quality of diagnostic testing is not diminished as testing moves increasingly away from the central laboratory (Shaw 2016). The general opinion indicated by this study (Question 14) represents the belief that, although POCT performance is adequate, it is not at a level that is on par with the instruments employed

in the central laboratory, which are considered to represent the gold standard in the diagnostic sector. When such performance is considered as being adequate, it should be noted that this translates as being adequate if the inherent limitations in the use of POCT in comparison to CLT are recognised. The clinical biosciences cohort, being closely aligned to the equipment utilised in the central laboratory, have a specific form of awareness of these limitations and hence a responsibility to make other healthcare professionals aware of these limitations. For example, previous research has pointed to the poor analytical performance of certain HbA1c devices (Lenters-Westra, Slingerland 2009) and places emphasis on the importance of being aware of the limitations of POCT devices in their effective utilisation. As such, those in the clinical biosciences profession, who are working regularly with central laboratory instruments, are most aware of the differences in levels of analytical performance between these instruments and POCT devices and so are perhaps best placed to direct their utilisation and hence uptake within the hospital environment.

As part of the consideration of device performance and data management issues, improved connectivity and the introduction of connectivity regulations in order to standardise the connectivity of devices was highlighted as being the third most common suggestion by the sample of clinical bioscientists with regards to potential solutions to overcoming issues of uptake/adoption (Question 25). It should be highlighted however, that in some healthcare systems connectivity standards do already exist, however it is the lack of standardisation of the interface between the devices and the clinical records that is the problem. Wiencek and Nichols (Wiencek, Nichols 2016) found that POCT devices from various manufacturers utilised proprietary communication protocols that require either separate computers and software to communicate results electronically or some form of middleware software solution. This can ultimately result in the need for separate computers and software for each type of POCT device used within a single hospital with obvious inefficiencies and comparability problems. Although there are now offerings by some manufacturers by way of POCT middleware to interface multiple devices, it would be substantially beneficial if a particular health system within a single location had one agreed and standardised interface that could be used by all POCT devices.

As indicated above, economic issues were regarded by clinical bioscientists as having the greatest impact upon POCT uptake within the hospital environment. A strong majority (89%) of participants in this study group believe that the cost per test of POCT is higher than CLT. This is a stark contrast to the clinicians within the US study group (Chapter 5), where 43% of individuals were of the belief that the cost per test of POCT was not higher than CLT. This reflects the fact that clinical biosciences staff are, in general, more aware of the economies of scale that are available from effective utilisation of the central laboratory services due to their close alignment

with it. As POCT is carried out on a one-off basis by an individual, rather than by using automation (as is the case for CLT), it is impossible for POCT to match that afforded by high-volume CLT (Lee-Lewandrowski, Lewandrowski 2009). In this regard, at an economic level, CLT is driven by providing significantly higher testing numbers than those carried out using POCT. The increased cost of POCT is cited here as being the second most relevant disadvantage of this particular type of testing, being indicated as such by 30% of study respondents. Interestingly however, the majority (71%) of participants were of the opinion that the use of a POCT system is cost-effective overall. This is a common finding throughout the 3 survey studies carried out as part of this research (UK, US and Clinical Biosciences). Hence, it is clear that, despite varying opinion on the cost per test of POCT, the consensus is that any increased cost incurred is justifiable and that POCT plays an important role within diagnostic pathways for patients within hospital healthcare systems. Debate however does exist as to exactly what is the role of POCT. The research carried out here, and in the studies presented in the previous chapters, addresses the proposition; is POCT an effective diagnostic asset in its own right? Or, is it simply a rapid screening test with limited diagnostic capabilities? What is important from the findings presented here is that the role of POCT must be clearly defined within a particular healthcare system in order for it to run effectively. For example, the British Committee for Standards in Haematology provide guidelines on use of haematological POCT, while the Medicines and Healthcare Products Regulatory Agency also provide recommendations for POCT in general. One of the key recommendations from both of these agencies is that those responsible for the provision of POCT within a healthcare organisation should clearly define the purpose of a particular test, including whether its role is as a defined diagnostic test or simply as a screening process, and whether it should be used for monitoring disease or as a method for determining a course of treatment (Boyd, Woolley 2016). The clinical opinion attained here clearly concurs that robust frameworks such as these are required in every healthcare system that wants to maximise the effectiveness of POCT in an evidenced-based manner.

Given that the responsibility for quality assurance of testing is associated with the professional practice of the clinical biosciences cohort, there was a much stronger opinion here on the issues caused by non-competent or untrained staff operating the POCT devices. This part of the study found that it is the dispersion of devices throughout the clinical system that is a main cause of such issues, with a very large majority “agreeing” (28%) or “strongly agreeing” (46%) with this proposition (Question 10a). These data reflected a stronger force of opinion than that found in the previous UK (Chapter 4) and US (Chapter 5) studies that include a majority of clinical specialists in each. The effects of inaccurate and/or poor quality tests that result from the use of POCT by untrained or non-competent staff was cited as being the most common disadvantage in this study (Question 23). Both the inexperience of clinical staff in terms of diagnostic testing

and a lack of awareness of the limitations of POCT were cited by participants here as contributing to this. As already discussed, awareness of the limitations of POCT in comparison to CLT is a vital component in deriving effective utilisation of a POCT system. While the use of satellite POCT laboratories has been suggested to overcome this problem, by allowing trained clinical biosciences professionals to operate the POCT devices throughout the clinical system, there are also issues with this approach, namely; there is increased cost associated with having trained laboratory professionals placed throughout the clinical system to perform the tests instead of nursing staff, and; the practicalities in situations where results are required immediately at the patient bedside to assist clinical decision making (Shaw 2016). Alternative potential solutions to overcoming this barrier to adoption, provided by participants in this study, included; increased and improved training processes (including periodic competency assessments), and; more involvement of the central laboratory in both the oversight of quality assurance procedures, maintenance and training. Whereas, some POCT devices have been developed to the extent that they contain many controls to negate quality issues that may result from operator error, many devices still are largely dependent on the competency of the individual carrying out the test, both in the execution of the test and reading/assessment of the result (Lewandrowski, Gregory et al. 2011). In order to further improve this situation, it would be beneficial to have a set of agreed standards that manufacturers adhere to for the development of their POCT devices, including regulations of the controls that can prevent (inexperienced) user error.

This study found that clinical biosciences professionals were of very strong opinion that “high” or “very high” levels of operator training and support on regulatory compliance were provided to device operators, which is seen as necessary for the effective use of POCT. By comparison, the data from the UK and US studies was much more varied across the scale. This variation in opinion between the clinical groups suggests that this support is not being provided on a wide enough level or, perhaps, not always to the correct individuals. The continued growth of POCT, along with its dispersion across numerous clinical settings, means that it will continue to exist as a regulatory focus and as a focal point of the struggle to comply with strict regulations (Dyhdalo, Howanitz et al. 2014).

Clinical bioscientists are stronger in their opinion that POCT increases the workload of front line clinical staff while individuals from other specialist areas tended to disagree that this was the case. The general consensus for this opinion from the other clinical specialists was that the time taken to carry out a test using POCT was less than that required to attain results from the central laboratory. It is possible that the clinical biosciences cohort is less aware of the time needed to transport samples to the central laboratory for testing and to wait on the findings. Furthermore,

clinicians place more of an importance on the timeliness of test result in comparison to test accuracy and/or reliability, while, to those in the clinical biosciences profession, accuracy and reliability are paramount (Pati, Singh 2014). Whereas, POCT can be seen as a method for shifting some of the central laboratory workload to other areas of the healthcare system (by moving the operation to other clinical professionals), it in fact can increase workload if not managed appropriately. For example, if tests are duplicated, i.e. both POCT and CLT are utilised and the POCT data is simply used for initial screening purposes, then the laboratory are carrying out the work to acquire data that may already exist. Therefore, paradoxically it may be the workload of the laboratory staff responsible for QA processes that may be increased as a result of the utilisation of POCT.

While, in the previous studies, the position within the health system of the various clinical participants were generally found to have little effect on responses to the key issues of interest, in the case of the clinical bioscientists cohort there was clear evidence of a common experience. Their increased responsibility with respect to the assuring quality of testing aligned to that provided by the central laboratory leads to them being more aware of issues within their specific area of work. Comparison of responses to specific quality assurance and regulatory issues (Question 13) indicated that in the UK study the “not relevant” category was the most cited for 4 of the 5 issues and in the US study it was the response category most cited across all 5 issues, while clinical bioscientists cited “not relevant” the least for 4 of the 5 issues stated. This was found to be a common theme across other related categories, as indicated in Questions 9, 17 and 21.

Overall, these data suggest that opinion on POCT utilisation is significantly influenced by the clinical background of the respondents, regardless of the health system in which they practice.

The body of work described in this chapter has completed the remaining research objectives as defined in Chapter 1, namely; to assess how the perception of issues effecting the uptake of POCT, including their impact and relevance, varies with respect to the specific clinical role, and; to determine the global experiences of clinical bioscientists, as the professional group most closely aligned to hospital based diagnostic testing, in relation to the identified barriers to adoption of POCT. By conducting this study on an international scale, any influences of underlying health model have been negated. Furthermore, the clinical opinion gathered here from clinical bioscientists has been mapped back onto the data collected from the previous 2 primary studies as described in Chapters 4 and 5. Additionally, this study was used to complete the data collection necessary to successfully accomplish the final 4 research objectives defined in Chapter 1; to identify the key advantages and potential benefits of POCT use within secondary healthcare; to identify the major disadvantages deemed to result from the use of POCT; to

determine the clinical areas/situations in which POCT can provide the most benefit in secondary care, and; to suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption? The study sample here has been used, along with the previous 2 study samples, to collate data to satisfy these objectives accordingly.

6.5 Statistical Comment

In the previous primary studies found in Chapters 4 and 5, a statistical analysis could be applied to determine if differences in opinion between clinical groups were statistically significant. The participants in this study were deliberately recruited from the one respondent group (clinical bioscientists) and, as such, the same process cannot be followed. However, a number of areas have been highlighted as observing differences in opinion in comparison to the previous studies, in which participants from the "clinicians" respondent group were in the majority. For completeness, the next chapter aims to investigate the study group as a whole, combining respondents from the studies in Chapters 4, 5 and 6, as a means of assessing, firstly; UK vs US clinicians and, secondly; clinicians vs clinical bioscientists. This will be achieved using statistical analysis tools as a means of validating the research findings.

Chapter 7

Statistical Analysis

7.1 Study Objective

As a means of extruding additional value from the primary studies conducted herein, inferential statistics are applied here to the accumulated response data in order to determine if the findings deducted are statistically significant. The purpose of this study is to ensure that the research findings are as robust as possible and, as such, clarify the conclusions and recommendations made as a result of this piece of work.

7.2 Study Development & Design

The association of categorical variables and the comparison of opinions between response groups is to be statistically analysed using the Chi-square test and the calculation of odds ratios with 95% confidence intervals. Calculation of p-values using the Chi-square test allows for the testing of a specific null hypothesis; a significant p-value (i.e. < 0.05) rejects the null hypothesis and, in doing so, gives insight into both the response groups analysed and the strength of the results. Odds ratios are used to further compare the responses of the various response groups, by dividing the odds of an event happening in one group by the odds of an event happening in the other. 95% confidence intervals are applied to provide a guidance on the true odds ratio; that the figure lies within this interval 95% of the time. This study is designed to analyse the entire participant group as a whole, first of all as a comparison of UK respondents vs US respondents and, secondly, as a comparison of clinicians vs clinical bioscientists. Inferential statistics are applied where relevant and, as such, questions where participants can give more than one answer or can offer a free response have been omitted from this process of analysis.

7.3 Study Results

Firstly, an analysis of UK vs US study respondents has been carried out here with the results summarised in Table 7.1. Use of the Chi-square test has been used to identify statistically significant differences in opinion between the study groups, with a p-value of <0.05 signifying such. Within this data set, 7 questions have been found to be indicating statistically significant responses between participants in the UK and in the US by way of this method of statistical analysis. Of these, 2 (Questions 2 and 3) relate to the demographics of the participants. When considering perceived levels of proficiency in the use of POCT (Question 2), the participants from the US were more likely to be at polar ends of the scale; either rating themselves as “highly

proficient" (i.e. recognised trainers) or having completed no training themselves at all. A p-value of 0.006 was returned here with odds ratios (UK to US) of 0.182 (95% confidence intervals of 0.046-0.714) for "not completed any training" and 0.227 (0.056-0.916) for "highly proficient" (i.e. recognised trainer). Considering Question 3, which concerns the use of POCT in the participants place of work, a p-value of 0.03 was returned as all UK participants answered positively to this question, while 2 individuals in the US took part in the study when POCT was not actually utilised within their own department.

4 areas of particular interest were identified here. Question 7a regards the increased cost per test of POCT in comparison to CLT. A p-value of 0.002 was found here, with the UK participants found to be of a stronger opinion that POCT is of a higher cost per test. Secondly; Question 15b returned a p-value of less than 0.0001. This was with regards to whether perceived poor levels of connectivity could affect the clinician's ability to deduct a timely and accurate diagnosis through the use of POCT. The US participants were found to be of a stronger opinion that the poor connectivity made it more difficult to make such a diagnosis. Thirdly; Question 21c, which asked participants if the inappropriate use of POCT was a relevant issue in their place of work, returned a p-value of 0.001. Here, the US clinicians were of a stronger opinion that this was not a relevant issue. Finally, 21e concerned the relevance of another specific issue; whether POCT was not utilised effectively due to a lack of an interdepartmental management structure and clear clinical governance, with a p-value of 0.034. Again, the US clinicians were found to be more of the opinion that this issue was not relevant in their place of work.

When considering the odds ratios where these significant differences have been identified, it can be seen that the odds ratio of a UK participant vs US participant agreeing that the cost per test of POCT is higher than CLT (Question 7a) is 6.612 (with 95% confidence intervals of 1.844 to 23.715). As the interval does not cross the line of no difference (i.e. 1) then we can deem this to be statistically significant. Similarly, for Question 21c, the odds ratio for UK vs US participants indicating the inappropriate use of POCT as being "not relevant" within their place of work is 0.142 (with 95% confidence intervals of 0.045 to 0.444). As such, again this can be determined as being statistically significant. As for Question 21e, the odds ratio for the "not relevant" response category was calculated as 0.168 (0.049-0.576), again being deemed statistically significant.

A p-value of 0.025 was found for Question 18b, however as only 3 participants from the US study answered this question, little value can be extruded here.

Table 7.1 – Statistical analysis of UK vs US study participants.

Question / Response	UK (x) (n=48)	US (y) (n=21)	P-Value	Odds Ratio (x/y)	95% Confidence Intervals	
2) How would you rate your own expertise in the practical use of a POCT device?			**0.006**			
Not yet completed training.	4 (8%)	7 (33%)		**0.182**	0.046	0.714
Use under supervision.	2 (4%)	0 (0%)		-	-	-
Basic level capability – Unsupervised use.	21 (44%)	5 (24%)		**2.489**	0.784	7.898
Competent – Unsupervised use and maintenance.	17 (35%)	3 (14%)		**3.290**	0.846	12.793
Highly proficient – Recognised trainer.	4 (8%)	6 (19%)		**0.227**	0.056	0.916
3) Are any point-of-care testing devices used to diagnose patients in your area of clinical practice/specialism?			**0.030**			
Yes	48 (100%)	19 (90%)		-	-	-
No	0 (0%)	2 (10%)		-	-	-
7a) Do you agree that the cost per test of POCT is higher than CLT?			**0.002**			
Yes	36 (75%)	7 (33%)		**6.612**	1.844	23.715
No	7 (15%)	9 (43%)		**0.151**	0.042	0.542
7bi) On a scale of 1 to 10, to what extent do you agree or disagree that, POCT provides longer term economic benefits e.g. reduced hospital stay, reduced outpatient appointments etc.			**0.633**			
Strongly Disagree	2 (4%)	2 (10%)		**0.413**	0.054	3.150
Disagree	3 (6%)	2 (10%)		**0.633**	0.098	4.100
Neutral	18 (38%)	5 (24%)		**1.920**	0.601	6.136
Agree	13 (27%)	8 (38%)		**0.604**	0.204	1.789
Strongly Agree	12 (25%)	4 (19%)		**1.417**	0.398	5.045
7c) Would you agree that the use of a POCT system is cost-effective?			**0.053**			
Yes	36 (75%)	18 (86%)		-	-	-
No	8 (17%)	0 (0%)		-	-	-
8a) On a scale of 1 to 10, to what extent do you agree or disagree that procurement, reimbursement and budgeting in your institution sufficiently accommodate the interdepartmental nature of POCT, especially where it is a shared resource?			**0.304**			
Strongly Disagree	5 (10%)	4 (19%)		**0.344**	0.079	1.502
Disagree	14 (29%)	1 (5%)		**6.323**	0.755	52.922
Neutral	12 (25%)	5 (24%)		**0.727**	0.206	2.565
Agree	10 (21%)	4 (19%)		**0.786**	0.205	3.010
Strongly Agree	4 (8%)	1 (5%)		**1.366**	0.141	13.271
8b) Does this lack of specific accommodation make it difficult to utilise POCT to its full potential in your institution?			**0.461**			
Yes	18 (38%)	5 (24%)		-	-	-

No	2 (4%)	0 (0%)		-	-	-
9a) Difficult to justify the use of POCT devices as the simple cost per test of POCT is higher than traditional CLT.			**0.324**			
Not relevant	13 (27%)	9 (43%)		**0.454**	0.153	1.346
Rarely relevant	5 (10%)	4 (19%)		**0.465**	0.111	1.953
Sometimes relevant	9 (19%)	3 (14%)		**1.308**	0.314	5.440
Fairly relevant	11 (23%)	2 (10%)		**2.676**	0.536	13.366
Very relevant	10 (21%)	2 (10%)		**2.368**	0.469	11.950
9b) Difficult to justify the implementation of a POCT system as the true cost-effectiveness of such a system is difficult to gauge and cost comparison studies against traditional central laboratory testing methods are complex.			**0.564**			
Not relevant	13 (27%)	6 (29%)		**0.867**	0.275	2.734
Rarely relevant	5 (10%)	3 (14%)		**0.659**	0.142	3.066
Sometimes relevant	6 (13%)	5 (24%)		**0.429**	0.114	1.613
Fairly relevant	13 (27%)	3 (14%)		**2.105**	0.528	8.389
Very relevant	11 (23%)	3 (14%)		**1.685**	0.416	6.831
9c) Difficult to justify the implementation of a POCT system as the initial costs of implementing such a system are high.			**0.058**			
Not relevant	14 (29%)	7 (33%)		**0.824**	0.274	2.475
Rarely relevant	4 (8%)	5 (24%)		**0.291**	0.069	1.220
Sometimes relevant	8 (17%)	6 (29%)		**0.500**	0.149	1.683
Fairly relevant	11 (23%)	0 (0%)		**-**	-	-
Very relevant	11 (23%)	3 (14%)		**1.784**	0.442	7.200
9d) Issues with regards to budget contributions towards POCT due to the allocation of separate budgets for separate departments which is not appropriate for interdepartmental nature of POCT.			**0.316**			
Not relevant	12 (25%)	9 (43%)		**0.419**	0.140	1.257
Rarely relevant	8 (17%)	1 (5%)		**3.897**	0.454	33.459
Sometimes relevant	11 (23%)	2 (10%)		**2.750**	0.550	13.749
Fairly relevant	9 (19%)	5 (24%)		**0.711**	0.204	2.470
Very relevant	7 (15%)	3 (14%)		**0.992**	0.229	4.299
9e) Difficulty in obtaining reimbursement for POCT. (i.e. who pays for the test?)			**0.457**			
Not relevant	20 (42%)	12 (57%)		**0.533**	0.183	1.556
Rarely relevant	2 (4%)	0 (0%)		**-**	-	-
Sometimes relevant	6 (13%)	1 (5%)		**2.923**	0.328	26.038
Fairly relevant	9 (19%)	2 (10%)		**2.250**	0.439	11.522
Very relevant	8 (17%)	5 (24%)		**0.649**	0.182	2.306
10a) On a scale of 1 to 10, to what extent do you agree or disagree that the dispersion of POCT devices through the healthcare system gives rise to opportunities for untrained or non-competent staff to use the devices, leading to an increased			**0.262**			

disregard of certain quality assurance steps and procedures, including quality control?					
Strongly Disagree	5 (10%)	6 (29%)	**0.271**	0.072	1.027
Disagree	7 (15%)	3 (14%)	**0.967**	0.223	4.191
Neutral	8 (17%)	1 (5%)	**3.800**	0.443	32.604
Agree	14 (29%)	6 (29%)	**0.961**	0.307	3.007
Strongly Agree	14 (29%)	4 (19%)	**1.647**	0.467	5.807
10b) Does the increased disregard of certain quality assurance steps and procedures that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.744**		
Yes	18 (38%)	7 (33%)	**0.771**	0.162	3.663
No	10 (21%)	3 (14%)	**1.296**	0.273	6.156
11a) On a scale of 1 to 10, to what extent do you agree or disagree that regulations for analytical testing accreditation for POCT are overly complex?			**0.904**		
Strongly Disagree	7 (15%)	4 (19%)	**0.650**	0.163	2.593
Disagree	9 (19%)	4 (19%)	**0.886**	0.232	3.390
Neutral	15 (31%)	4 (19%)	**1.806**	0.499	6.534
Agree	8 (17%)	4 (19%)	**0.765**	0.196	2.979
Strongly Agree	3 (6%)	1 (5%)	**1.231**	0.119	12.736
11b) Does the burden imposed by such requirements that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.210**		
Yes	8 (17%)	2 (10%)	**4.000**	0.431	37.109
No	3 (6%)	3 (14%)	**0.250**	0.027	2.319
12a) On a scale of 1 to 10, how much operator training and support on regulatory compliance for POCT are provided by your central laboratory?			**0.140**		
Very Low	9 (19%)	7 (33%)	**0.297**	0.087	1.010
Low	3 (6%)	0 (0%)	**-**	-	-
Neutral	13 (27%)	1 (5%)	**5.571**	0.667	46.510
High	11 (23%)	5 (24%)	**0.654**	0.187	2.290
Very High	12 (25%)	3 (14%)	**1.444**	0.351	5.947
12b) Does this lack of training and support that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT?			**0.061**		
Yes	4 (8%)	5 (24%)	**0.160**	0.021	1.192
No	10 (21%)	2 (10%)	**6.250**	0.839	46.571
13a) Errors due to incorrect quality assurance steps or procedures by untrained or non-competent staff operating the POCT devices.			**0.118**		
Not relevant	12 (25%)	11 (52%)	**0.272**	0.091	0.817
Rarely relevant	20 (42%)	4 (19%)	**2.857**	0.829	9.842
Sometimes relevant	8 (17%)	3 (14%)	**1.133**	0.268	4.799

Fairly relevant	4 (8%)	0 (0%)	-	-	-
Very relevant	4 (8%)	2 (10%)	**0.818**	0.137	4.870
13b) Complex accreditation regulations written for traditional laboratory instrumentation are blindly applied to modern POCT devices, causing issues for non-laboratory operators.			**0.824**		
Not relevant	19 (40%)	6 (29%)	**1.101**	0.325	3.733
Rarely relevant	7 (15%)	2 (10%)	**1.200**	0.219	6.587
Sometimes relevant	6 (13%)	3 (14%)	**0.611**	0.131	2.855
Fairly relevant	7 (15%)	3 (14%)	**0.733**	0.162	3.329
Very relevant	3 (6%)	0 (0%)	-	-	-
13c) Issues with maintaining compliance with regulatory requirements due to a number of changes in the accreditation regulations.			**0.100**		
Not relevant	18 (38%)	10 (48%)	**0.277**	0.075	1.022
Rarely relevant	6 (13%)	0 (0%)	-	-	-
Sometimes relevant	9 (19%)	0 (0%)	-	-	-
Fairly relevant	9 (19%)	4 (19%)	**0.643**	0.163	2.534
Very relevant	2 (4%)	0 (0%)	-	-	-
13d) Issues with maintaining compliance with regulatory requirements due to the dispersed nature of POCT devices making them difficult to control.			**0.931**		
Not relevant	18 (38%)	7 (33%)	**0.692**	0.207	2.317
Rarely relevant	4 (8%)	1 (5%)	**1.300**	0.133	12.696
Sometimes relevant	5 (10%)	1 (5%)	**1.667**	0.178	15.608
Fairly relevant	11 (23%)	4 (19%)	**0.833**	0.217	3.200
Very relevant	6 (13%)	1 (5%)	**2.053**	0.225	18.687
13e) A lack of development of POCT devices, caused by product approval hurdles discouraging economic investment in their development.			**0.100**		
Not relevant	16 (33%)	14 (67%)	**0.245**	0.079	0.763
Rarely relevant	5 (10%)	2 (10%)	**1.154**	0.204	6.524
Sometimes relevant	7 (15%)	1 (5%)	**3.595**	0.412	31.392
Fairly relevant	10 (21%)	3 (14%)	**1.667**	0.405	6.864
Very relevant	6 (13%)	0 (0%)	-	-	-
14a) On a scale of 1 to 10, how do you rate the level of analytical performance (i.e. specificity, sensitivity & precision) of a POCT device in comparison to a traditional CLT instrument?			-		
Very Low	0 (0%)	0 (0%)	-	-	-
Low	1 (2%)	0 (0%)	-	-	-
Neutral	7 (15%)	4 (19%)	**0.640**	0.164	2.503
High	22 (46%)	11 (52%)	**0.615**	0.210	1.800
Very High	18 (38%)	4 (19%)	**2.250**	0.646	7.839
14b) Does the reduced analytical performance that you have indicated in part (a) make it more difficult			-		

to make a timely and reliable diagnosis in comparison to utilising CLT?						
Yes	0 (0%)	0 (0%)		-	-	-
No	0 (0%)	0 (0%)		-	-	-
15a) On a scale of 1 to 10, how do you rate the connectivity (i.e. to the central healthcare and patient record systems) and data management of a POCT system in comparison to a traditional CLT instrument?			**0.127**			
Very Poor	17 (35%)	4 (19%)		**2.056**	0.588	7.189
Poor	16 (33%)	3 (14%)		**2.667**	0.677	10.509
Neutral	4 (8%)	5 (24%)		**0.255**	0.060	1.081
Good	3 (6%)	3 (14%)		**0.356**	0.065	1.944
Excellent	8 (17%)	4 (19%)		**0.750**	0.197	2.861
15b) Does the poor connectivity and data management that you have indicated in part (a) make it more difficult to make a timely & reliable diagnosis in comparison to utilising CLT?			**<0.0001**			
Yes	8 (17%)	7 (33%)		-	-	-
No	26 (54%)	0 (0%)		-	-	-
16a) On a scale of 1 to 10, how do you rate the difficulty of performing tests using POCT devices compared to that of a CLT system?			-			
Very Easy	33 (69%)	16 (76%)		**0.737**	0.226	2.404
Easy	6 (13%)	2 (10%)		**1.390**	0.256	7.536
Neutral	3 (6%)	3 (14%)		**0.409**	0.075	2.221
Difficult	5 (10%)	0 (0%)		-	-	-
Very Difficult	0 (0%)	0 (0%)		-	-	-
16bi) Does the increased difficulty that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT?			-			
Yes	2 (4%)	0 (0%)		-	-	-
No	3 (6%)	0 (0%)		-	-	-
17a) POCT devices producing reduced analytical performance in comparison to traditional centralised testing.			**0.929**			
Not relevant	21 (44%)	8 (38%)		**1.167**	0.404	3.371
Rarely relevant	13 (27%)	5 (24%)		**1.114**	0.337	3.684
Sometimes relevant	10 (21%)	5 (24%)		**0.789**	0.231	2.697
Fairly relevant	3 (6%)	2 (10%)		**0.600**	0.092	3.896
Very relevant	1 (2%)	0 (0%)		-	-	-
17b) POCT system poorly connected to main healthcare and patient record systems, causing data management issues.			**0.058**			
Not relevant	8 (17%)	8 (38%)		**0.300**	0.093	0.970
Rarely relevant	10 (21%)	2 (10%)		**2.368**	0.469	11.950
Sometimes relevant	13 (27%)	3 (14%)		**2.105**	0.528	8.389

Fairly relevant	7 (15%)	0 (0%)	**-**	-	-
Very relevant	10 (21%)	7 (33%)	**0.489**	0.154	1.548
17c) POCT device operators encountering difficulties with their use.		**-**			
Not relevant	18 (38%)	16 (76%)	**0.150**	0.043	0.519
Rarely relevant	11 (23%)	3 (14%)	**1.685**	0.416	6.831
Sometimes relevant	11 (23%)	0 (0%)	**-**	-	-
Fairly relevant	8 (17%)	1 (5%)	**3.800**	0.443	32.604
Very relevant	0 (0%)	0 (0%)	**-**	-	-
18a) On a scale of 1 to 10, to what extent do you agree or disagree that POCT significantly increases the workload of front line clinical staff (i.e. device operators)?		**0.857**			
Strongly Disagree	18 (38%)	8 (38%)	**0.975**	0.339	2.806
Disagree	13 (27%)	5 (24%)	**1.189**	0.362	3.903
Neutral	7 (15%)	5 (24%)	**0.546**	0.151	1.975
Agree	5 (10%)	1 (5%)	**2.326**	0.255	21.234
Strongly Agree	5 (10%)	2 (10%)	**1.105**	0.197	6.209
18b) Does the increased workload that you have indicated in part (a) reduce staff satisfaction levels in comparison to when utilising CLT?		**0.025**			
Yes	6 (13%)	3 (14%)	**-**	-	-
No	13 (27%)	0 (0%)	**-**	-	-
19a) On a scale of 1 to 10, to what extent do you agree or disagree that the central laboratory are reluctant to allow the control of testing to be passed on?		**0.272**			
Strongly Disagree	10 (21%)	5 (24%)	**0.757**	0.220	2.608
Disagree	7 (15%)	1 (5%)	**3.150**	0.360	27.531
Neutral	14 (29%)	2 (10%)	**3.606**	0.733	17.736
Agree	9 (19%)	6 (29%)	**0.513**	0.153	1.721
Strongly Agree	7 (15%)	5 (24%)	**0.490**	0.134	1.796
19b) Does the resistance that you have indicated in part (a) act as an impediment to the more widespread adoption of POCT within the clinical environment?		**0.794**			
Yes	14 (29%)	9 (43%)	**0.778**	0.117	5.162
No	4 (8%)	2 (10%)	**1.286**	0.194	8.534
20a) On a scale of 1 to 10, to what extent do you agree or disagree that the clinical care pathway and role of the central laboratory have been altered sufficiently to incorporate the use of POCT?		**0.585**			
Strongly Disagree	3 (6%)	4 (19%)	**0.273**	0.055	1.354
Disagree	6 (13%)	2 (10%)	**1.317**	0.242	7.163
Neutral	12 (25%)	4 (19%)	**1.371**	0.383	4.917
Agree	16 (33%)	6 (29%)	**1.204**	0.389	3.731
Strongly Agree	10 (21%)	4 (19%)	**1.081**	0.295	3.965

20b) Does this poor integration of POCT that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.205**			
Yes	3 (6%)	4 (19%)		**0.250**	0.028	2.237
No	6 (13%)	2 (10%)		**4**	0.447	35.789
21a) Reduced staff satisfaction levels and increased friction between staff groups.			**-**			
Not relevant	25 (52%)	15 (71%)		**0.455**	0.150	1.375
Rarely relevant	11 (23%)	1 (5%)		**6.111**	0.734	50.855
Sometimes relevant	8 (17%)	2 (10%)		**1.949**	0.377	10.083
Fairly relevant	3 (6%)	3 (14%)		**0.409**	0.075	2.221
Very relevant	0 (0%)	0 (0%)		**-**	-	-
21b) The resistance of central laboratory to allow the control of testing to be passed on acts as an impediment to the more widespread uptake of POCT.			**0.112**			
Not relevant	17 (35%)	7 (33%)		**0.940**	0.312	2.836
Rarely relevant	7 (15%)	2 (10%)		**1.451**	0.273	7.710
Sometimes relevant	11 (23%)	0 (0%)		**-**	-	-
Fairly relevant	5 (10%)	5 (24%)		**0.326**	0.082	1.292
Very relevant	8 (17%)	5 (24%)		**0.560**	0.157	1.999
21c) Inappropriate use of POCT (i.e. over-use and reliance on test results, undermining clinical expertise).			**0.001**			
Not relevant	9 (19%)	13 (62%)		**0.142**	0.045	0.444
Rarely relevant	8 (17%)	0 (0%)		**-**	-	-
Sometimes relevant	13 (27%)	2 (10%)		**3.529**	0.720	17.304
Fairly relevant	11 (23%)	1 (5%)		**5.946**	0.715	49.447
Very relevant	7 (15%)	5 (24%)		**0.546**	0.151	1.975
21d) The full benefits of POCT are not being realised as significant alterations to clinical care pathways and the central laboratory are required.			**0.674**			
Not relevant	22 (46%)	12 (57%)		**0.634**	0.225	1.785
Rarely relevant	10 (21%)	3 (14%)		**1.579**	0.387	6.447
Sometimes relevant	5 (10%)	3 (14%)		**0.698**	0.151	3.233
Fairly relevant	10 (21%)	2 (10%)		**2.500**	0.497	12.570
Very relevant	1 (2%)	1 (5%)		**0.426**	0.025	7.145
21e) POCT system does not run efficiently as an interdepartmental management structure is required with clear clinical governance for POCT.			**0.034**			
Not relevant	20 (42%)	17 (81%)		**0.168**	0.049	0.576
Rarely relevant	7 (15%)	0 (0%)		**-**	-	-
Sometimes relevant	6 (13%)	2 (10%)		**1.357**	0.251	7.352
Fairly relevant	11 (23%)	1 (5%)		**5.946**	0.715	49.447
Very relevant	4 (8%)	1 (5%)		**1.818**	0.191	17.323

21f) Reluctance to change within health services and a lack of evidence justifying POCT makes it hard to justify the implementation of such a system.			**0.383**		
Not relevant	10 (21%)	5 (24%)	**0.842**	0.248	2.859
Rarely relevant	8 (17%)	1 (5%)	**4.000**	0.467	34.239
Sometimes relevant	15 (31%)	4 (19%)	**1.932**	0.554	6.733
Fairly relevant	8 (17%)	6 (29%)	**0.500**	0.149	1.683
Very relevant	7 (15%)	5 (24%)	**0.546**	0.151	1.975
26) Please rank the following categories of issues in order of current impact on POCT adoption, using the table below (from 1 to 4 where 1 is most current impact and 4 is least current impact).*			**0.389**		
Economic Issues	123	65	**0.781**	0.544	1.121
Quality Assurance & Regulatory Issues	123	46	**1.259**	0.853	1.858
Device Performance & Data Management Issues	105	41	**1.180**	0.786	1.773
Staff & Operational Issues	99	48	**0.893**	0.602	1.324
***Scoring system used: 1st place rank = 4 points, 2nd = 3 points, 3rd = 2 points, 4th = 1 point.**					

A process of analysis has also been carried out comparing study participants from the clinicians group against those from the clinical bioscientists group. All 3 primary studies have been included in this investigation; the UK study (Chapter 4), the US study (Chapter 5) and the Clinical Bioscientists study (Chapter 6). As before, the Chi-square test has been applied in order to calculate p-values to identify where differences in response between the 2 study groups can be determined as having a statistically significant differentiation. Results are summarised in Table 7.2. There are 30 identified areas where a significant difference in response is indicated.

The first area concerns the perceived expertise of study respondents, with a p-value of less than 0.0001 calculated. By assessment of the odds ratios, it is seen that the odds ratio of a clinician determining themselves as being highly proficient in the use of POCT (i.e. a recognised trainer) in comparison to a participant from the other study group is 0.058 (95% confidence intervals 0.020-0.170).

2 parts of Question 7 (a and c), which focus on the economics of POCT, are indicated as having statistically significant differences in their responses. Question 7a, which asks participants if they agreed that POCT was of a higher cost per test in comparison to POCT, returned a p-value of 0.007. The clinicians were found to be less likely to agree with this notion, with an odds ratio (clinicians to clinical bioscientists) calculated for agreement as 0.319 (0.136-0.746). Question 7c asked participants if they thought the use of a POCT system was cost-effective; a p-value of 0.037 was calculated here, indicating a statistically significant difference in response. The clinicians were found more likely to be in agreement that this was true, with an odds ratio of 2.683 (1.034-6.962) returned.

A statistically significant p-value of 0.037 was observed for Question 8b, however the resulting odds ratios were not found to be statistically significant. As such, and due to the decreased participation in this question, little value can be extruded here. This question asked those participants who did not believe that procurement, reimbursement and budgeting in their institution sufficiently accommodated the interdepartmental nature of POCT if this perceived lack of accommodation made it more difficult for POCT to realise its full potential.

4 parts of Question 9 (a, b, c and e) have been determined as being statistically significant in terms of response differentiation. This question considers opinion on the relevance of certain economic issues within the participant's place of work. The p-values returned here are <0.0001, 0.001, 0.001 and <0.0001 respectively. For all 4 parts noted here, the clinicians group provide a much stronger response in the "not relevant" category, with calculated odds ratios (in comparison to clinical bioscientists) and confidence limits of; 6.438 (2.602-15.929), 5.827 (2.343-14.492), 5.794 (2.334-14.385) and 6.892 (3.216-14.771).

A significant difference in response was found with respect to agreement with how the dispersed nature of POCT contributes to misuse of the devices, leading to quality issues (Question 10a), with a p-value of 0.0003 indicating such. The clinical bioscientists study group were found to be much more likely to strongly agree with this statement. The odds ratio of clinicians to clinical bioscientists responding in this category was calculated as being 0.221 (0.101-0.484).

Levels of operator training and support on regulatory compliance provided by the central laboratory was another area where a significant disparity in response was observed (Question 12a). Here, a p-value of 0.0004 was returned by way of the Chi-square test. The clinicians were found to be much less likely to respond in the "very high" category here, with an odds ratio in comparison to the clinical bioscientists of 0.216 (0.093-0.502). The second part of this question (12b) was also an area where a significant difference in response was observed, with a p-value of 0.018 calculated. This question asked those participants who ranked levels of training and support as "low" or "very low" if this made it more difficult to attain a timely and reliable diagnosis as a result. The clinicians were found more likely to indicate that this was, in fact, not the case, with an odds ratio here of 6.000 (1.274-28.255).

All 5 parts of Question 13 (a, b, c, d and e) were found to indicate significant differences in responses between the 2 study groups; these were in relation to the relevance of quality assurance and regulatory issues in the participant's place of work. P-values calculated were <0.0001, <0.0001, <0.0001, <0.0001 and 0.004. Clinicians were found to be of much stronger opinion that the specific issues were "not relevant", with calculated odds ratios and confidence

limits in this response category of 8.167 (3.030-22.008), 7.583 (3.292-17.470), 14.034 (5.603-35.151), 14.873 (5.470-40.441) and 2.416 (1.171-4.987).

Significantly different response profiles were also found with respect to opinion on the level of analytical performance of POCT in comparison to CLT instruments (Question 14a), with a p-value of less than 0.0001 calculated. The clinicians were found to be much more likely to rate the levels of performance as very high. The odds ratio for this category of response was calculated as being 5.167 (2.206-12.101).

Both parts of Question 15 were also found to be statistically significant in terms of the differential in response profile between the 2 study groups (p-values of 0.004 and <0.0001 correspondingly). This question was with respect to the levels of connectivity and data management of a POCT system in comparison to CLT. The clinicians were found to be more likely to rank connectivity and data management as being "very low" with an odds ratio in comparison to the clinical bioscientists of 3.222 (1.486-6.987). Furthermore, of the participants who ranked the connectivity and data management capabilities of POCT as being low or very low, clinicians here were found to be much more likely to indicate that the reduced levels of connectivity and data management made it more difficult to attain a timely and accurate diagnosis. The odds ratio here (clinicians to clinical bioscientists) was calculated as being 0.093 (0.028-0.301).

All 3 parts of Question 17 (a, b and c) were further identified as areas of significant differentiation between response profiles of the participant groups. This question was in relation to the relevance of specific device performance and data management issues in the participant's place of work. The p-values calculated here were <0.0001, 0.009 and <0.0001 respectively. As previously, when considering questions regarding the relevance of specific issues, the clinicians were found to be much more likely to respond in the "not relevant" category, in comparison to the clinical bioscientists. The odds ratios here were found to be 12.500 (4.707-33.197), 4.727 (1.686-13.256) and 16.399 (6.186-43.470).

The workload of front line clinical staff (Question 18a) was found to be an area of disparity also (p-value <0.0001) with clinicians much less likely to "agree" or "strongly agree" that the utilisation of POCT increased the workload of front line clinical staff, in comparison to CLT. The calculated odds ratios (clinicians to clinical bioscientists) for these categories were 0.291 (0.105-0.807) and 0.159 (0.046-0.553) respectively. The second part of this particular question (18b) was also identified as being an area of particular interest, with a p-value of 0.022. Of all the participants who believed that POCT did increase the workload of front-line clinical staff, the clinicians here were found to be less likely to agree that this increased workload resulted in

reduced staff satisfaction levels. The calculated odds ratio for this response was 0.256 (0.077-0.853).

Furthermore, of the study participants who "disagreed" or "strongly disagreed" that the clinical care pathway and role of the central laboratory had been altered sufficiently to incorporate the use of POCT (Question 20b), the clinicians were less likely to agree that this lack of accommodation made it more difficult to attain a timely and reliable diagnosis. The p-value calculated here was 0.025 and odds ratio 0.156 (0.029-0.845).

The final area where a statistically significant difference in response profile between clinicians and clinical bioscientists was observed within 5 parts of Question 21 (a, b, c, d and e). Question 21 was focused on attaining clinical opinion on the relevance of specific staff and operational issues within the participant's place of work. Application of the Chi-square test, as previously, returned p-values of <0.0001, 0.037, 0.0003, <0.0001 and 0.0003 respectively. Once more the clinicians were observed to be of a stronger opinion of finding these specific issues as "not relevant" within their place of work. Calculation of odds ratios ratifies this notion, with the comparison of clinicians against clinical bioscientists here found to be 7.489 (3.596-15.595), 1.722 (0.828-3.585), 7.125 (2.634-19.273), 8.273 (3.680-18.600) and 4.680 (2.286-9.584) respectively. The exception here is Question 21b where the odds ratio is not statistically significant as it crosses the threshold of no difference (i.e. 1).

Table 7.2 – Statistical analysis of Clinicians vs Clinical Bioscientists across 3 primary studies.

Question / Response	**Clinicians (x) (n=58)**	**Clinical Bioscientists (y) (n=112)**	**P-Value**	**Odds Ratio (x/y)**	**95% Confidence Intervals**	
2) How would you rate your own expertise in the practical use of a POCT device?			**<0.0001**			
Not yet completed training.	9 (16%)	13 (12%)		**1.399**	0.560	3.497
Use under supervision.	1 (2%)	1 (1%)		**1.947**	0.120	31.711
Basic level capability – Unsupervised use.	26 (45%)	14 (13%)		**5.688**	2.653	12.192
Competent – Unsupervised use and maintenance.	18 (31%)	21 (19%)		**1.950**	0.939	4.051
Highly proficient – Recognised trainer.	4 (7%)	63 (56%)		**0.058**	0.020	0.170
3) Are any point-of-care testing devices used to diagnose patients in your area of clinical practice/specialism?			**0.073**			
Yes	56 (97%)	98 (88%)		**3.714**	0.809	17.059
No	2 (3%)	13 (12%)		**0.269**	0.059	1.237
7a) Do you agree that the cost per test of POCT is higher than CLT?			**0.007**			
Yes	34 (59%)	99 (88%)		**0.319**	0.136	0.746
No	14 (24%)	13 (12%)		**3.136**	1.341	7.333

7bi) On a scale of 1 to 10, to what extent do you agree or disagree that, POCT provides longer term economic benefits e.g. reduced hospital stay, reduced outpatient appointments etc.			**0.700**		
Strongly Disagree	4 (7%)	9 (8%)	**0.848**	0.250	2.880
Disagree	5 (9%)	9 (8%)	**1.080**	0.344	3.384
Neutral	19 (33%)	35 (31%)	**1.072**	0.544	2.112
Agree	14 (24%)	37 (33%)	**0.645**	0.314	1.324
Strongly Agree	16 (28%)	22 (20%)	**1.558**	0.743	3.269
7c) Would you agree that the use of a POCT system is cost-effective?			**0.037**		
Yes	46 (79%)	80 (71%)	**2.683**	1.034	6.962
No	6 (10%)	28 (25%)	**0.373**	0.144	0.967
8a) On a scale of 1 to 10, to what extent do you agree or disagree that procurement, reimbursement and budgeting in your institution sufficiently accommodate the interdepartmental nature of POCT, especially where it is a shared resource?			**0.399**		
Strongly Disagree	7 (12%)	18 (16%)	**0.823**	0.320	2.118
Disagree	13 (22%)	24 (21%)	**1.244**	0.572	2.708
Neutral	16 (28%)	22 (20%)	**1.861**	0.874	3.964
Agree	11 (19%)	34 (30%)	**0.622**	0.285	1.360
Strongly Agree	3 (5%)	11 (10%)	**0.569**	0.151	2.135
8b) Does this lack of specific accommodation make it difficult to utilise POCT to its full potential in your institution?			**0.037**		
Yes	20 (34%)	30 (27%)	**7.333**	0.877	61.334
No	1 (2%)	11 (10%)	**0.136**	0.016	1.141
9a) Difficult to justify the use of POCT devices as the simple cost per test of POCT is higher than traditional CLT.			**<0.0001**		
Not relevant	19 (33%)	8 (7%)	**6.438**	2.602	15.929
Rarely relevant	5 (9%)	12 (11%)	**0.793**	0.265	2.374
Sometimes relevant	12 (21%)	40 (36%)	**0.473**	0.225	0.997
Fairly relevant	9 (16%)	37 (33%)	**0.375**	0.166	0.846
Very relevant	12 (21%)	14 (13%)	**1.848**	0.791	4.315
9b) Difficult to justify the implementation of a POCT system as the true cost-effectiveness of such a system is difficult to gauge and cost comparison studies against traditional central laboratory testing methods are complex.			**0.001**		
Not relevant	18 (31%)	8 (7%)	**5.827**	2.343	14.492
Rarely relevant	7 (12%)	8 (7%)	**1.768**	0.607	5.150
Sometimes relevant	9 (16%)	30 (27%)	**0.494**	0.216	1.129
Fairly relevant	14 (24%)	34 (30%)	**0.718**	0.347	1.485
Very relevant	9 (16%)	29 (26%)	**0.517**	0.226	1.185

9c) Difficult to justify the implementation of a POCT system as the initial costs of implementing such a system are high.			**0.001**			
Not relevant	18 (31%)	8 (7%)		**5.794**	2.334	14.385
Rarely relevant	8 (14%)	20 (18%)		**0.728**	0.299	1.772
Sometimes relevant	11 (19%)	39 (35%)		**0.432**	0.201	0.927
Fairly relevant	10 (17%)	28 (25%)		**0.618**	0.276	1.381
Very relevant	11 (19%)	16 (14%)		**1.390**	0.598	3.230
9d) Issues with regards to budget contributions towards POCT due to the allocation of separate budgets for separate departments which is not appropriate for interdepartmental nature of POCT.			**0.118**			
Not relevant	17 (29%)	17 (15%)		**2.410**	1.117	5.200
Rarely relevant	8 (14%)	15 (13%)		**1.067**	0.423	2.691
Sometimes relevant	12 (21%)	33 (29%)		**0.645**	0.302	1.374
Fairly relevant	13 (22%)	23 (21%)		**1.157**	0.535	2.502
Very relevant	6 (10%)	23 (21%)		**0.459**	0.175	1.203
9e) Difficulty in obtaining reimbursement for POCT. (i.e. who pays for the test?)			**<0.0001**			
Not relevant	28 (48%)	15 (13%)		**6.892**	3.216	14.771
Rarely relevant	2 (3%)	20 (18%)		**0.175**	0.039	0.779
Sometimes relevant	7 (12%)	28 (25%)		**0.441**	0.179	1.089
Fairly relevant	9 (16%)	20 (18%)		**0.910**	0.384	2.159
Very relevant	8 (14%)	28 (25%)		**0.515**	0.217	1.224
10a) On a scale of 1 to 10, to what extent do you agree or disagree that the dispersion of POCT devices through the healthcare system gives rise to opportunities for untrained or non-competent staff to use the devices, leading to an increased disregard of certain quality assurance steps and procedures, including quality control?			**0.0003**			
Strongly Disagree	11 (19%)	7 (6%)		**3.314**	1.206	9.103
Disagree	10 (17%)	6 (5%)		**3.475**	1.192	10.134
Neutral	9 (16%)	11 (10%)		**1.585**	0.615	4.088
Agree	17 (29%)	29 (26%)		**1.099**	0.540	2.238
Strongly Agree	10 (17%)	51 (46%)		**0.221**	0.101	0.484
10b) Does the increased disregard of certain quality assurance steps and procedures that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.903**			
Yes	17 (29%)	45 (40%)		**0.944**	0.376	2.373
No	10 (17%)	25 (22%)		**1.059**	0.421	2.661
11a) On a scale of 1 to 10, to what extent do you agree or disagree that regulations for analytical testing accreditation for POCT are overly complex?			**0.132**			
Strongly Disagree	8 (14%)	17 (15%)		**1.000**	0.398	2.511
Disagree	12 (21%)	13 (12%)		**2.282**	0.951	5.474
Neutral	16 (28%)	26 (23%)		**1.462**	0.692	3.086

Agree	8 (14%)	30 (27%)		**0.480**	0.201	1.146
Strongly Agree	4 (7%)	16 (14%)		**0.489**	0.154	1.550
11b) Does the burden imposed by such requirements that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.517**			
Yes	9 (16%)	26 (23%)		**1.615**	0.375	6.951
No	3 (5%)	14 (13%)		**0.619**	0.144	2.664
12a) On a scale of 1 to 10, how much operator training and support on regulatory compliance for POCT are provided by your central laboratory?			**0.0004**			
Very Low	15 (26%)	10 (9%)		**3.577**	1.479	8.651
Low	3 (5%)	5 (4%)		**1.153**	0.265	5.019
Neutral	13 (22%)	11 (10%)		**2.652**	1.096	6.414
High	15 (26%)	31 (28%)		**0.893**	0.431	1.852
Very High	8 (14%)	46 (41%)		**0.216**	0.093	0.502
12b) Does this lack of training and support that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT?			**0.018**			
Yes	8 (14%)	12 (11%)		**0.167**	0.035	0.785
No	12 (21%)	3 (3%)		**6.000**	1.274	28.255
13a) Errors due to incorrect quality assurance steps or procedures by untrained or non-competent staff operating the POCT devices.			**<0.0001**			
Not relevant	19 (33%)	6 (5%)		**8.167**	3.030	22.008
Rarely relevant	22 (38%)	22 (20%)		**2.343**	1.150	4.771
Sometimes relevant	11 (19%)	34 (30%)		**0.492**	0.227	1.069
Fairly relevant	3 (5%)	23 (21%)		**0.196**	0.056	0.684
Very relevant	2 (3%)	19 (17%)		**0.163**	0.0364	0.726
13b) Complex accreditation regulations written for traditional laboratory instrumentation are blindly applied to modern POCT devices, causing issues for non-laboratory operators.			**<0.0001**			
Not relevant	23 (40%)	12 (11%)		**7.583**	3.292	17.470
Rarely relevant	7 (12%)	24 (21%)		**0.591**	0.234	1.490
Sometimes relevant	7 (12%)	28 (25%)		**0.481**	0.193	1.199
Fairly relevant	8 (14%)	25 (22%)		**0.657**	0.271	1.592
Very relevant	1 (2%)	14 (13%)		**0.141**	0.018	1.109
13c) Issues with maintaining compliance with regulatory requirements due to a number of changes in the accreditation regulations.			**<0.0001**			
Not relevant	26 (45%)	8 (7%)		**14.034**	5.603	35.151
Rarely relevant	6 (10%)	15 (13%)		**0.838**	0.304	2.314
Sometimes relevant	5 (9%)	33 (29%)		**0.247**	0.089	0.680
Fairly relevant	10 (17%)	32 (29%)		**0.584**	0.259	1.315

Very relevant	1 (2%)	15 (13%)		**0.125**	0.016	0.974
13d) Issues with maintaining compliance with regulatory requirements due to the dispersed nature of POCT devices making them difficult to control.			**<0.0001**			
Not relevant	23 (40%)	6 (5%)		**14.873**	5.470	40.441
Rarely relevant	5 (9%)	15 (13%)		**0.682**	0.233	2.000
Sometimes relevant	6 (10%)	22 (20%)		**0.526**	0.198	1.397
Fairly relevant	13 (22%)	34 (30%)		**0.754**	0.353	1.608
Very relevant	1 (2%)	26 (23%)		**0.063**	0.008	0.480
13e) A lack of development of POCT devices, caused by product approval hurdles discouraging economic investment in their development.			**0.004**			
Not relevant	21 (36%)	22 (20%)		**2.416**	1.171	4.987
Rarely relevant	6 (10%)	26 (23%)		**0.378**	0.145	0.986
Sometimes relevant	7 (12%)	29 (26%)		**0.388**	0.157	0.959
Fairly relevant	13 (22%)	11 (10%)		**2.718**	1.122	6.584
Very relevant	6 (10%)	15 (13%)		**0.749**	0.273	2.058
14a) On a scale of 1 to 10, how do you rate the level of analytical performance (i.e. specificity, sensitivity & precision) of a POCT device in comparison to a traditional CLT instrument?			**<0.0001**			
Very Low	0 (0%)	4 (4%)		-	-	-
Low	1 (2%)	19 (17%)		**0.080**	0.010	0.618
Neutral	7 (12%)	24 (21%)		**0.470**	0.188	1.173
High	28 (48%)	46 (41%)		**1.239**	0.645	2.379
Very High	20 (34%)	10 (9%)		**5.167**	2.206	12.101
14b) Does the reduced analytical performance that you have indicated in part (a) make it more difficult to make a timely and reliable diagnosis in comparison to utilising CLT?			-			
Yes	0 (0%)	16 (14%)		-	-	-
No	0 (0%)	7 (6%)		-	-	-
15a) On a scale of 1 to 10, how do you rate the connectivity (i.e. to the central healthcare and patient record systems) and data management of a POCT system in comparison to a traditional CLT instrument?			**0.004**			
Very Poor	20 (34%)	15 (13%)		**3.222**	1.486	6.987
Poor	15 (26%)	17 (15%)		**1.829**	0.832	4.023
Neutral	7 (12%)	23 (21%)		**0.491**	0.196	1.229
Good	6 (10%)	24 (21%)		**0.390**	0.149	1.021
Excellent	8 (14%)	23 (21%)		**0.572**	0.237	1.381
15b) Does the poor connectivity and data management that you have indicated in part (a) make it more difficult to make a timely & reliable diagnosis in comparison to utilising CLT?			**<0.0001**			
Yes	12 (21%)	27 (24%)		**0.093**	0.028	0.301

No	24 (41%)	5 (4%)		**10.800**	3.321	35.123
16a) On a scale of 1 to 10, how do you rate the difficulty of performing tests using POCT devices compared to that of a CLT system?			**0.066**			
Very Easy	40 (69%)	49 (44%)		**2.545**	1.279	5.062
Easy	7 (12%)	29 (26%)		**0.352**	0.143	0.867
Neutral	6 (10%)	13 (12%)		**0.805**	0.288	2.249
Difficult	4 (7%)	9 (8%)		**0.780**	0.229	2.655
Very Difficult	0 (0%)	2 (2%)		**-**	-	-
16bi) Does the increased difficulty that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT?			**0.679**			
Yes	2 (3%)	3 (3%)		**1.667**	0.147	18.875
No	2 (3%)	5 (4%)		**0.600**	0.053	6.795
17a) POCT devices producing reduced analytical performance in comparison to traditional centralised testing.			**<0.0001**			
Not relevant	25 (43%)	6 (5%)		**12.500**	4.707	33.197
Rarely relevant	15 (26%)	16 (14%)		**1.920**	0.867	4.252
Sometimes relevant	12 (21%)	39 (35%)		**0.431**	0.203	0.913
Fairly relevant	4 (7%)	21 (19%)		**0.291**	0.095	0.896
Very relevant	1 (2%)	20 (18%)		**0.073**	0.010	0.561
17b) POCT system poorly connected to main healthcare and patient record systems, causing data management issues.			**0.009**			
Not relevant	13 (22%)	6 (5%)		**4.727**	1.686	13.256
Rarely relevant	10 (17%)	16 (14%)		**1.144**	0.481	2.720
Sometimes relevant	14 (24%)	20 (18%)		**1.335**	0.614	2.901
Fairly relevant	7 (12%)	24 (21%)		**0.455**	0.182	1.135
Very relevant	13 (22%)	36 (32%)		**0.542**	0.258	1.135
17c) POCT device operators encountering difficulties with their use.			**<0.0001**			
Not relevant	29 (50%)	6 (5%)		**16.399**	6.186	43.470
Rarely relevant	11 (19%)	21 (19%)		**0.911**	0.403	2.057
Sometimes relevant	9 (16%)	33 (29%)		**0.386**	0.169	0.881
Fairly relevant	8 (14%)	24 (21%)		**0.524**	0.218	1.259
Very relevant	0 (0%)	17 (15%)		**-**	-	-
18a) On a scale of 1 to 10, to what extent do you agree or disagree that POCT significantly increases the workload of front line clinical staff (i.e. device operators)?			**<0.0001**			
Strongly Disagree	22 (38%)	14 (13%)		**3.841**	1.771	8.331
Disagree	17 (29%)	18 (16%)		**1.935**	0.904	4.141
Neutral	11 (19%)	19 (17%)		**1.022**	0.448	2.331
Agree	5 (9%)	25 (22%)		**0.291**	0.105	0.807

Strongly Agree	3 (5%)	26 (23%)		**0.159**	0.046	0.553
18b) Does the increased workload that you have indicated in part (a) reduce staff satisfaction levels in comparison to when utilising CLT?			**0.022**			
Yes	5 (9%)	32 (29%)		**0.256**	0.077	0.853
No	11 (19%)	18 (16%)		**3.911**	1.173	13.045
19a) On a scale of 1 to 10, to what extent do you agree or disagree that the central laboratory are reluctant to allow the control of testing to be passed on?			**0.960**			
Strongly Disagree	11 (19%)	20 (18%)		**1.025**	0.451	2.332
Disagree	8 (14%)	14 (13%)		**1.070**	0.419	2.734
Neutral	13 (22%)	27 (24%)		**0.860**	0.401	1.842
Agree	12 (21%)	25 (22%)		**0.860**	0.393	1.881
Strongly Agree	11 (19%)	16 (14%)		**1.344**	0.575	3.142
19b) Does the resistance that you have indicated in part (a) act as an impediment to the more widespread adoption of POCT within the clinical environment?			**0.183**			
Yes	19 (33%)	24 (21%)		**2.217**	0.678	7.252
No	5 (9%)	14 (13%)		**0.451**	0.138	1.476
20a) On a scale of 1 to 10, to what extent do you agree or disagree that the clinical care pathway and role of the central laboratory have been altered sufficiently to incorporate the use of POCT?			**0.844**			
Strongly Disagree	6 (10%)	7 (6%)		**1.563**	0.499	4.900
Disagree	7 (12%)	10 (9%)		**1.260**	0.452	3.515
Neutral	15 (26%)	32 (29%)		**0.759**	0.368	1.565
Agree	17 (29%)	33 (29%)		**0.863**	0.427	1.745
Strongly Agree	12 (21%)	18 (16%)		**1.215**	0.537	2.747
20b) Does this poor integration of POCT that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT?			**0.025**			
Yes	5 (9%)	12 (11%)		**0.156**	0.029	0.845
No	8 (14%)	3 (3%)		**6.400**	1.183	34.614
21a) Reduced staff satisfaction levels and increased friction between staff groups.			**<0.0001**			
Not relevant	36 (62%)	19 (17%)		**7.489**	3.596	15.595
Rarely relevant	10 (17%)	22 (20%)		**0.774**	0.337	1.774
Sometimes relevant	8 (14%)	43 (38%)		**0.224**	0.096	0.521
Fairly relevant	3 (5%)	13 (12%)		**0.380**	0.104	1.396
Very relevant	0 (0%)	5 (4%)		**-**	-	-
21b) The resistance of central laboratory to allow the control of testing to be passed on acts as an impediment to the more widespread uptake of POCT.			**0.037**			
Not relevant	18 (31%)	22 (20%)		**1.722**	0.828	3.585

Rarely relevant	9 (16%)	27 (24%)	**0.532**	0.230	1.230
Sometimes relevant	9 (16%)	26 (23%)	**0.560**	0.241	1.298
Fairly relevant	9 (16%)	20 (18%)	**0.785**	0.331	1.864
Very relevant	11 (19%)	7 (6%)	**3.317**	1.206	9.125
21c) Inappropriate use of POCT (i.e. over-use and reliance on test results, undermining clinical expertise).			**0.0003**		
Not relevant	18 (31%)	6 (5%)	**7.125**	2.634	19.273
Rarely relevant	8 (14%)	13 (12%)	**1.083**	0.420	2.791
Sometimes relevant	14 (24%)	23 (21%)	**1.079**	0.505	2.308
Fairly relevant	10 (17%)	31 (28%)	**0.470**	0.211	1.049
Very relevant	8 (14%)	28 (25%)	**0.417**	0.176	0.990
21d) The full benefits of POCT are not being realised as significant alterations to clinical care pathways and the central laboratory are required.			**<0.0001**		
Not relevant	29 (50%)	11 (10%)	**8.273**	3.680	18.600
Rarely relevant	11 (19%)	22 (20%)	**0.851**	0.379	1.910
Sometimes relevant	6 (10%)	33 (29%)	**0.241**	0.094	0.618
Fairly relevant	11 (19%)	24 (21%)	**0.761**	0.342	1.693
Very relevant	1 (2%)	12 (11%)	**0.132**	0.017	1.039
21e) POCT system does not run efficiently as an interdepartmental management structure is required with clear clinical governance for POCT.			**0.0003**		
Not relevant	30 (52%)	19 (17%)	**4.680**	2.286	9.584
Rarely relevant	7 (12%)	19 (17%)	**0.600**	0.236	1.526
Sometimes relevant	7 (12%)	24 (21%)	**0.446**	0.179	1.111
Fairly relevant	11 (19%)	22 (20%)	**0.851**	0.379	1.910
Very relevant	3 (5%)	18 (16%)	**0.255**	0.072	0.905
21f) Reluctance to change within health services and a lack of evidence justifying POCT makes it hard to justify the implementation of such a system.			**0.597**		
Not relevant	10 (17%)	12 (11%)	**1.545**	0.622	3.837
Rarely relevant	8 (14%)	21 (19%)	**0.610**	0.251	1.481
Sometimes relevant	18 (31%)	26 (23%)	**1.298**	0.636	2.648
Fairly relevant	11 (19%)	25 (22%)	**0.711**	0.321	1.579
Very relevant	11 (19%)	17 (15%)	**1.156**	0.500	2.674
26) Please rank the following categories of issues in order of current impact on POCT adoption, using the table below (from 1 to 4 where 1 is most current impact and 4 is least current impact).*			**0.469**		
Economic Issues	164	244	**1.073**	0.848	1.357
Quality Assurance & Regulatory Issues	141	224	**0.979**	0.766	1.250
Device Performance & Data Management Issues	124	222	**0.837**	0.650	1.076
Staff & Operational Issues	121	170	**1.145**	0.881	1.488

***Scoring system used: 1st place rank = 4 points, 2nd = 3 points, 3rd = 2 points, 4th = 1 point.**

7.4 Discussion

It was noted in Chapter 5 that responses from US participants in the study differed from those in the UK in 2 particular areas; namely the cost per test of POCT and with regards to the connectivity and data management capabilities of POCT. A statistical analysis by way of the Chi-square test and calculation of odds ratios has been conducted in order to assess if these differences are indeed statistically significant and if any other significant differences in response have been observed. Differences in response regarding the cost per test of POCT (Question 7a) have been found to be statistically significant here. UK study participants were found to be more likely to agree that the cost per test of POCT is higher than CLT. As was discussed in Chapter 5, it is possible that the opinion of the US study participants is influenced by the levels of reimbursement found within the US healthcare system and the privatisation of central laboratories. It is apparent that reimbursement is made for laboratory tests and that POCT is incorporated into this process, i.e. as a responsibility of the central laboratory, and so receives the same level of reimbursement as the equivalent CLT (which often is a minimal amount). As a result, from the clinician's point of view, the cost of a specific test has no difference to them whether it is performed by CLT or POCT. It was also found by the primary study conducted in Chapter 5 that the privatisation of the central laboratory service can in some cases cause CLT to be more expensive to the patient than POCT.

The study conducted in Chapter 5 found that US participants suggested levels of connectivity were much more varied within their health system in comparison to the UK. The difference in response profile was with regard to whether those participants who believed levels of connectivity and data management of POCT were poor subsequently believed that this made it more difficult to attain a timely and reliable diagnosis (Question 15b). The analysis here has proven this difference in response to be statistically significant. The US participants were found to believe that the perceived poor levels of connectivity and data management did not affect their ability to attain a sufficient quality of diagnosis (while UK participants were in stronger agreement that they did). The main issue for the US participants was found to be with respect to the loss of access to diagnostic data via the patient record systems when using of POCT.

The statistical analysis conducted has identified one further area where a statistically significant disparity in response profile between UK and US participants has been observed; namely, the relevance of 2 specific staff and operational issues within the participant's place of work; the inappropriate use of POCT (i.e. over-use and reliance on test results, undermining clinical expertise) and the inefficient use of POCT due to a lack of an interdepartmental management structure and clear clinical governance. The US participants were found to be much more likely to indicate these specific issues as being "not relevant" in comparison to the UK response profile.

The reasoning for this is perhaps the utility of POCT within the US health system. The primary study conducted in Chapter 5 has found indications that POCT is used as a screening tool rather than as a standalone diagnostic solution that ultimately could replace CLT. As such, the nature of its use within the US health system would make it less likely to be seen as being over-used or relied upon, or further to undermine clinical expertise. Additionally, use as a screening tool could potentially simplify the requirement for clearer clinical governance.

With 48 UK participants and 21 US participants amalgamated from the first 2 primary studies (Chapters 4 and 5) it is perhaps difficult to ascertain statistically significant differentiation with such a size of sample. The increased participation attained through the study carried out in Chapter 6 allowed for a substantially increased sample size to be assessed when considering Clinicians (n=58) as a comparison against Clinical Bioscientists (n=112) across all 3 primary studies. Much of the disparity in response profiles found here was with regards to the relevance of specific issues within the participant's place of work. This was indicated as a constant disconnect in Chapter 6 in comparison to the previous studies. Consistently, it was observed that the clinicians were much more likely to suggest that specific issues were "not relevant" in comparison to the response data from the clinical bioscientists. In fact, of the 30 areas where a statistically significant difference in response was found here, this accounted for 17 of such instances. The clear disconnect in the perception of relevance of specific issues is a major barrier to the uptake of POCT within secondary care. In order to overcome barriers there must be a clear agreement on what actually exists in reality between those who are responsible for the utility of POCT and those who are responsible for test quality assurance. The clinical bioscientists are perhaps more acutely aware of the relevance of specific issues due to the responsibility that they hold with respect to the assurance of test quality and accuracy within healthcare systems.

Further areas of response identified within Chapter 6 as being dissimilar to the previous studies (which held a majority of clinician participation) included the dispersion of devices leading to untrained / non-competent users operating the devices, ultimately resulting in quality assurance issues, levels of operator training and support on regulatory compliance provided by the central laboratory and the increased workload of front-line clinical staff as a result of the utilisation of POCT. By way of statistical analysis, the work carried out here has confirmed these differences in response between the 2 study groups as being statistically significant (Questions 10a, 12a, 12b, 18a and 18b).

Clinical bioscientists were found to be much more likely to "strongly agree" with the notion that the dispersed nature of devices ultimately leads to issues with test quality due to incorrect operation of the POCT machines and instruments. Being substantially more familiar with the

traditional CLT method, this study group are hence further aware of the benefits of confining testing to a highly specialised team of operators. As such, they are perhaps more acutely mindful of the risks to test quality borne as a result of providing access across a much wider (and less specialised) workforce.

Furthermore, the clinical bioscientists were found to rate the levels of operator training and support on regulatory compliance provided by the central laboratory significantly higher than the clinician group of participants. It is to be expected that those providing a service will be more inclined to be of the opinion that the service being provided is of a sufficient level. This variation in opinion between the clinical groups suggests that this support is not being provided on a wide enough level or, perhaps, not always to the correct individuals. However, clinicians of the opinion that levels of support and training were "low" or "very low" were less likely to agree (in comparison to clinical bioscientists of the same opinion) that this made it more difficult for them to attain a timely and reliable diagnosis. As was indicated in Chapter 4, a detailed analysis and consideration of comments made by face-to-face responders in the first primary (UK) study suggested that poor levels of support by the central laboratory are not necessarily considered to be a barrier to the uptake of POCT. In fact, the majority of responders in this study suggested that much of the training (and support) is actually provided by the device manufacturers themselves, rather than the central laboratory.

Clinical bioscientists were found to be of stronger opinion also that POCT increased the workload of front-line clinical staff. As discussed in the previous chapters, the consensus (for clinicians) to disagree with this opinion was, in general, that the time taken to carry out a test using POCT was less than that required to attain results via the CLT method. The possibility remains that the clinical biosciences cohort is less aware of the time burden endured to transport samples to the central laboratory for testing and the subsequent wait for test results. Furthermore, it has been suggested that clinicians place more of an importance on the timeliness of test result in comparison to test accuracy and/or reliability, while, to those in the clinical biosciences profession, accuracy and reliability are paramount (Pati, Singh 2014). Whereas, POCT can be seen as a method for shifting some of the central laboratory workload to other areas of the healthcare system (by moving the operation to other clinical professionals), it in fact can increase workload if not managed appropriately. Paradoxically, it may be the workload of the laboratory staff responsible for QA processes that may be increased as a result of the utilisation of POCT.

The analysis conducted here has identified further areas where a statistically significant difference in opinion has been observed between clinicians and clinical bioscientists. Firstly, the levels of analytical performance provided by POCT devices in comparison to CLT instruments;

clinicians were found much more likely to rate the level of analytical performance as being “very high”. Those in the clinical biosciences profession, who are working regularly with CLT instruments, are perhaps most aware of the differences in levels of analytical performance between these instruments and POCT devices. Whereas POCT can produce clinically acceptable results, which to clinicians can translate as being “high” or “very high” in terms of performance, the “gold standard” in terms of diagnostic testing (i.e. the CLT instrumentation) can perform at a much higher level, often above and beyond what is required in terms of clinical acceptability.

Secondly, differences in response were observed with respect to the connectivity and data management capabilities of POCT. Clinicians were found to be more likely to rate such capabilities of POCT as being “very poor”. However, of those participants who perceived such capabilities to be “poor” or “very poor”, it was the clinical bioscientists who were of stronger opinion that this subsequently made it more difficult to attain a timely and reliable diagnosis. As those responsible for the utility of POCT, the clinicians are more likely to experience issues with connectivity and data management. However, their use as a tool in “real-time” for quick decisions in time-critical situations hence lends itself to the opinion amongst this clinical group that these issues don’t necessarily translate into an issue with respect to the deduction of an accurate and timely diagnosis.

Thirdly, statistically significant differences in opinion were found with respect to the economics of POCT. Clinical bioscientists were, perhaps unsurprisingly, found to be of a stronger opinion that POCT is of a higher cost per test than CLT. As indicated previously, within Chapter 6, economic issues were regarded by clinical bioscientists as having the greatest impact upon POCT uptake within the hospital environment. This reflects the fact that clinical biosciences staff are, in general, more aware of the economies of scale that are available from effective utilisation of the central laboratory services due to their close alignment with it. The increased cost of POCT was cited in the clinical biosciences primary study as being the second most relevant disadvantage of POCT. Similarly, the clinicians were of a stronger opinion that the use of POCT was cost-effective (despite any perceived increases in costs). Again, this perhaps is a consequence of the fact that clinicians, by virtue of their role, place more of an importance on the timeliness of test result in comparison to test accuracy and/or reliability. As such, the value of POCT is higher and hence it is seen as being more cost-effective in comparison to someone from the clinical biosciences cohort, who is more likely to place more importance on test accuracy and/or reliability.

The process of a systematic statistical analysis reveals the significance of the demographics between the clinicians and clinical bioscientists. It has been demonstrated (Question 2) that the clinical bioscientists are further inclined to rate themselves as being “highly proficient” in the

use of POCT (i.e. recognised trainers), while the most common category for the clinicians was "basic level capability" (i.e. unsupervised use). It is hence apparent that levels of proficiency in use and/or training capability may influence perception of barriers to adoption of POCT. Ultimately, the analysis conducted here endorses the deduction propositioned in Chapter 6 that opinion on POCT utilisation is significantly influenced by the clinical background of the respondents, regardless of the health system in which they practice.

Chapter 8

Conclusions & Recommendations for Further Work

8.1 Conclusions

The work presented in this thesis provides the findings from a major body of research which seeks to define, categorise and prioritise the barriers to adoption of POCT within hospital-based healthcare. The core issues are considered in a manner that also considers solutions by which these barriers may be overcome. In doing so, the work addresses for the first time how both the healthcare funding system and respective clinical roles can affect opinions (and in some cases perceptions) of the core issues which impact upon POCT adoption and its subsequent utilisation.

With respect to the key objectives of the research, a substantial systematic review of the relevant academic literature has identified the specific issues most pertinent to POCT adoption within hospital-based healthcare, allowing them to be categorised accordingly and hence satisfying the first two objectives of the research as defined in Chapter 1; to determine from a systematic review of the academic literature the actual issues that affect the adoption of POCT devices within the hospital-based clinical environment, and; to categorise the issues identified from the literature as a means of understanding in detail their relative contribution to adoption of POCT devices in the hospital environment. Based on the information garnered from the literature reviewed herein (2000 to 2016), economic issues and quality assurance and regulatory considerations were the joint most highly cited barriers to hospital-based POCT adoption. The next most important aspects relate to device performance and data management issues with operational issues then somewhat further behind in terms of the number of citations in the literature during the review period. The number of publications in the reviewed literature that relate to each of the barriers was assessed as an indication of their respective relevance in terms of impact upon POCT adoption in hospital-delivered care. This exercise was carried out by way of satisfying the third research objective described in Chapter 1; to determine, in order of priority, which issues are currently impacting the adoption of POCT devices within the clinical environment.

The outcomes from this 16-year longitudinal systematic review was then used as the basis of a primary study wherein the opinion of clinicians was obtained on the nature and scale of the barriers to adoption of POCT identified from the literature. The findings from the core part of this primary study has engaged a range of clinicians and clinical bioscientists from UK hospitals,

as presented in Chapter 4. The focus of this study was to accomplish the fourth research objective; to determine the relationship between those issues identified from a consideration of the academic literature and the opinions of clinicians within the UK healthcare environment on the same issues. By way of satisfying the fifth research objective (to compare and contrast clinical perspectives (opinions) on those issues that are seen as impediments to the uptake of POCT from clinicians working in the UK healthcare system, i.e. that is free at the point of delivery, with those in the US system where the cost of healthcare provision is insurance-based), the UK outcomes from the survey tool concerned have then been compared with the experiences of a small cohort of US practitioners (Chapter 5). Finally, a more detailed consideration of the specific opinions of clinical bioscientists was undertaken with the respondents representing international perspectives (Chapter 6). The study executed here focused on attaining the sixth and seventh research objectives; to assess how the perception of issues effecting the uptake of POCT, including their impact and relevance, varies with respect to the specific clinical role, and; to determine the global experiences of clinical bioscientists, as the professional group most closely aligned to hospital based diagnostic testing, in relation to the identified barriers to adoption of POCT. Overall, the body of clinical professionals who participated across the 3 interrelated components of the study have provided validation for the ranking of both economic and quality assurance/regulatory issues as having the highest impact upon POCT uptake (as considered from the systematic literature review). Device performance and data management issues were ranked as being of less importance by clinicians when compared to the opinions of the clinical biosciences cohort. Clearly, the data gathered directly from the clinical professionals indicates that the debate with respect to the utility of POCT has still not been resolved. Notwithstanding these on-going issues with adoption in hospital-based care settings, POCT usage is still expected to grow in the coming years due to the increased decentralisation of healthcare and technological improvements that will continue the trend towards increased home-monitoring (Abel 2015).

The primary research undertaken here was purposefully shaped to determine the relationship between the issues identified in the academic literature and the opinions of clinical professionals acting within the UK National Health Service (NHS), which exists as a unique system providing healthcare to patients free at the point of delivery (i.e. Research Objective 4). The UK clinical professionals sampled indicated that economic issues have the most impact upon POCT adoption. The UK commits a significantly lower proportion of Gross Domestic Product (GDP) to healthcare compared to other developed nations, with reasons for this being twofold; firstly, the NHS is undoubtedly a lean and efficient model of healthcare provision in comparison to that operating in many other developed nations and, secondly; low levels of financial commitment to healthcare is an entrenched and established trend in the UK, which many experts believe has

resulted in many NHS providers currently being in deficit and described as being in "crisis" (Harding, Pritchard 2016). With this in mind, the perception of economic issues having the greatest impact upon POCT adoption within NHS hospitals is both insightful and logical. In general, UK clinicians agreed that POCT is associated with increased testing costs as compared to those undertaken via the central laboratory testing (CLT) services in the NHS. As such, significant debate exists with regard to the true value of POCT in terms of the assessment of these increased costs compared to the possible clinical benefits that this type of near patient of testing can provide, for example in terms of enhanced turnaround time (TAT) for the management of critically ill patients.

While regulations to ensure test accreditation were raised as issues with respect to both their complexity and appropriateness for POCT, the opinion of both UK clinicians, and subsequently also those in the US study, has highlighted a lack of knowledge by many clinicians in respect to the specifics involved. This was seen as ambiguity in participant responses across both studies, leading to significant variation in opinion and high numbers of non-responses. Many of the problems with regulation have been attributed to errors in readings from POCT devices. This is particularly an issue for "waived" tests in the US where regulatory steps (i.e. trained operators, internal quality control assessment, quality assurance programmes and external quality assessment) are not a requirement with clinicians finding themselves unfamiliar with the specifics of the regulatory requirements as a result. By definition, a waived test is one deemed to be "so simple and accurate to perform that the likelihood of erroneous results could be negligible". However, studies have shown that significant numbers of misclassifications of warfarin patients and misleading blood glucose level results have resulted from the use of waived POCT to deliver these type of test data (Plebani 2009). In Europe, the regulatory framework of simply using the CE Marking process to ensure that medical devices conform with basic health, safety and environmental standards is also seen as being weak in the context of ensuring that POCT test data is correct.

It is important to consider whether the barriers identified by literature, and subsequently validated by clinical opinion, are unique to POCT or pertain to the uptake of new technologies within secondary care more generally. With reduced healthcare budgets globally, it is obvious that the adoption of any technology is increasingly prioritised based on an economic evaluation of its utilisation. Furthermore, there are known to be certain difficulties in the assessment of healthcare technologies with respect to the provision of efficacy evidence (Chapman, Taylor et al. 2014). However, both these economic considerations and those of quality assurance & regulatory issues (and other barriers to adoption for that matter) are exaggerated when considering POCT due to the existence of an acceptable service in the central laboratory that

often POCT will run alongside and, in some cases, duplicate. As such, these barriers are considered to be unique in their existence with respect to POCT. Another characteristic of POCT leads itself to complications in regard to the utilisation of new technologies; multiplexing i.e. the ability to simultaneously measure multiple analytes on the same cartridge or test. Multi-analyte devices are more desirable with the increasing decentralisation of healthcare. However, the number of these types of POCT device is known to be low (bar critical care devices such as blood gas analysers) (St John, Price 2014). Therefore, while the introduction and uptake of new technologies into healthcare have their own difficulties, the combination of these technologies to produce multi-analyte devices adds an additional complication with respect to uptake, unique to POCT.

While the ranking (and associated importance) of many of the barriers to adoption of POCT found in the literature review were validated by UK clinicians as being relevant within the NHS, in several cases there were pronounced differences. It was apparent from the literature that, although the use of POCT can displace some of the workload of the central laboratory to other areas of the hospital, this could result in increased workloads of front-line clinical staff who are already stretched within a busy and hectic role. Moreover, previous work indicated that this led to high levels of stress and reduced staff satisfaction in the case of a significant proportion of operators/clinicians. However, the findings from the primary part of the research, as indicated in the opinions of both the UK and US clinicians, pointedly contradicts this notion. In particular, the UK respondents noted that the elimination of the reliance on a chain of services, i.e. sample transport and testing at the central laboratory site, allowing the clinicians to take control of diagnostic testing, has in fact been shown to reduce their workload and improve staff satisfaction. This is clearly an important finding for the future adoption of these technologies and could provide a means to justify their clinical utility as long as appropriate training and quality assurance processes are in place.

While usability and analytical performance of POCT devices have been found to be historical issues through the longitudinal systematic literature review study, clinicians based within both the UK and US healthcare systems have categorically stated that in the present day neither of these aspects remain an issue. Although it is not clear what has caused this change in opinion, the research carried out here has provided the first direct evidence based on primary data that demonstrates the evolution and advancements of the relevant test devices and technologies.

The research carried out within the UK clinical cohort also provides noteworthy insight into another of the significant issues of POCT adoption that has a historical context; connectivity and data management. While previous research has indicated that these aspects of POCT performance are poor in comparison to solutions from CLT, the research outcomes attained

here have suggested that, in the NHS, poor connectivity and data management does not necessarily transfer itself into an impediment to its adoption within hospital-based care. Given that POCT has the most benefit in time-critical situations when it can be used to manage patient care at an earlier intervention, it does not have to rely on historical data or previous test results to be clinically effective. As such, a consideration of where POCT should be positioned within the care pathway would suggest that connectivity and data management are strictly not significant barriers to the adoption of POCT in such circumstances.

While previous academic work has addressed barriers to adoption of POCT, none to date has investigated the impact of the model of healthcare funding on clinical uptake. In this work, the opinions of the UK clinicians working within the NHS (free to users at the point of delivery) have been compared with those working within the US system of healthcare (insurance-based) to determine relationships and identify any disconnects (i.e. Research Objective 5). It has been found here that in the US the role of insurance acts as an additional hurdle with regards to POCT uptake. The role of the insurers within the US system of healthcare makes reimbursement processes more complex with both insurers and patients playing an increased role with respect to the pathway of care. Furthermore, the fragmented nature of the US system makes it more difficult to implement centralised budgets or procurement policies with respect to POCT of the type that are typical of the UK system. The role of insurers also acts to mask the true costs of the POCT diagnostics, with many clinicians unsure of the true cost per test. This is reflected in the fact that more respondents disagreed (43%) than agreeing (33%) that a POCT test was more expensive than that from CLT. It is therefore suggested that the economic issues that have been shown to be of significance with respect to impact upon POCT adoption need to be considered in the context of the underlying healthcare funding model.

The research outcomes presented here have also identified that privatised laboratories operating in the US can affect the usage of POCT in comparison to the processes that operate in the UK, particularly with respect to providing guidance on regulatory requirements and training/support for the use of the devices. While the UK has moved towards engaging with the private sector in recent decades, it does not have the same reliance on outsourced provision as is the case for the US system (Guimares, de Carvalho 2011). This research suggests that private laboratories see POCT as competition and hence will not actively support it. Private laboratories are very common in the US, perhaps in part due to the relatively low qualification requirements for medical laboratory technicians and assistants in the US. In fact, only 12 states in the US licence such professions, while Clinical Laboratory Improvements Amendments (CLIA) only requires an Associate degree and little experience in order to perform highly complex tests (Rohde, Falleur et al. 2015). In addition, the more decentralised nature of US healthcare was

found to cause connectivity issues and hence a heightened impact upon POCT utilisation, in comparison to the UK environment.

An interesting finding from the research in this thesis is the fundamental classification of POCT in the US, in that it is seen generally as a screening test, rather than a standalone diagnostic solution (equivalent to CLT testing). The study findings here indicate that, although US participants to the survey agreed with the UK clinicians that POCT did not result in increased workload for clinical staff, their reasoning for this was different. The US clinicians suggested that a sample would always be taken and sent to the central laboratory regardless of whether POCT was used or not. Moreover, when POCT was used to ascertain a certain parameter, the laboratory sample would be used for other test parameters, even if they were available through use of the POCT test/device. This major finding is reflective of the operational aspects of the "free at point of delivery" NHS compared to the insurance-based model that is prevalent in the US. The US study participants indicated that POCT testing would only generally be used for a diagnostic parameter if the clinical situation absolutely required an instantaneous result.

This research also investigated the influence of clinical speciality on perspectives on barriers to adoption of POCT (i.e. Research Objective 6). By assessment of the responses by both UK and US samples, it was apparent that there was a disconnect in opinion of those responsible for the quality assurance of POCT, i.e. the Clinical Biosciences cohort, and those solely responsible for its operation and utilisation in the clinical areas of hospitals. Differences in opinion between these clinical groups was found to be present with respect to quality-related issues, such as; the decentralised nature of POCT resulting in its use by untrained/non-competent staff; overly complex analytical testing accreditation regulations; levels of training and support provided by the central laboratory, and the reluctance of the central laboratory service to release control of testing outside of CLT locations, i.e. on wards and in the Emergency Room/Department (ER/D) etc. The nature of this part of the research, which concerns 2 very different healthcare systems (i.e. UK and US) has provided a validation that key disconnects in clinical opinion exist irrespective of the underlying healthcare funding model, and hence ratifies the hypothesis that clinical role influences perspective on POCT uptake.

The research was further developed to investigate, in detail, the role of the clinical bioscientist, i.e. the clinical role most aligned with diagnostic testing with respect to barriers to POCT adoption (i.e. Research Objective 7). The survey tool for this element of the work was implemented internationally without any consideration of the influence of respective healthcare funding systems upon participant perspectives. To the best of the authors knowledge, no previous work has been identified that incorporates a study investigating a specific clinical role with respect to the barriers to adoption of POCT at this scale. One of the

most noteworthy findings here was that, for this specialist cohort, device performance and data management issues had, at least as much impact upon POCT uptake as quality assurance and regulatory issues. The inherent responsibility of the clinical laboratory service to make device operators aware of the limitations of POCT is paramount in this regard. While the analytical capabilities of POCT cannot match those of the more sophisticated instruments found in the central laboratory, the outputs from such devices are enough for them to be considered clinically acceptable in terms of providing a useful test result and the consequent clinical diagnosis upon which subsequent treatment is based. However, a sound understanding of the limitations of POCT is vital to ensure the overall quality and effectiveness of the attendant clinical outcome. The perspective of the clinical biosciences cohort was that quality-related issues were deemed to be of more importance than was the case for the other clinicians.

Being most associated with diagnostic testing, clinical bioscientists are aware of the associated economies of scale associated with CLT. As such, issues, such as the cost per test, were signified as being of increased importance in comparison to the perspectives of some other clinicians. In a broad sense, reimbursement for diagnostic testing is based on test complexity; a product of reagent cost and resource investment in performing the test. Hence, cost per test and automation have always been a major focus of laboratory medicine in respect of their role in sustaining an effective business model (St John, Price 2013). Consequently, the economics of testing are a higher priority to the clinical bioscientists than the immediacy of result.

The attributes of testing upon which the clinical cohorts place priority differs with respect to timeliness of the data (which the front-line clinician prioritises) and quality/accuracy of result (the priority of the clinical bioscientists). While the clinical bioscientists viewed POCT as increasing workload of clinical staff, due to the displacement of the testing from the central laboratory to the ward or ER/D, the clinicians did not agree with this due to the time required to retrieve CLT results. Hence, this research has demonstrated that POCT can actually increase the workload of the central laboratory service rather than that of the clinical staff, due to the responsibility of the laboratory to perform quality assurance activities. Furthermore, as indicated earlier, this research has found that POCT is used (broadly speaking) as a screening tool rather than a diagnostic solution in the US system of healthcare and as such duplicates testing, resulting in a further increased workload for the central laboratory. Hence, a fundamental conclusion of this research relates to the importance of defining both the role of POCT within a specific healthcare system, i.e. standalone diagnostic asset or rapid screening tool and the purpose of specific tests within the clinical care pathway.

The 3 clinical-based primary studies conducted have, together, acted to achieve the eighth, ninth, tenth and eleventh research objectives, as defined in Chapter 1, specifically; to identify

the key advantages and potential benefits of POCT use within secondary healthcare; to identify the major disadvantages deemed to result from the use of POCT; to determine the clinical areas/situations in which POCT can provide the most benefit in secondary care, and; to suggest how the most significant barriers to adoption of POCT in the relevant secondary healthcare systems can be overcome based on the findings of the studies undertaken, i.e. what are the possible solutions that may encourage more effective adoption? All 3 studies were designed to collect this data and through assessment and amalgamation findings have been identified as described herein.

The eighth objective of this research was to identify, in the opinion of study participants, the key advantages that POCT offers, specifically within the hospital-based environment. The most commonly cited advantages from participants were; rapid test TAT and associated earlier clinical intervention; more efficient patient management, including reduced hospital lengths of stay and a decreased number of outpatient appointments; improved patient/operator satisfaction and convenience, including lower volumes of blood required as samples and increased buy-in/responsibility, and; improved quality of care resulting overall in better patient outcomes. As such, this study has been able to define those situations in which POCT provides most benefit and hence satisfy the tenth research objective, including; the diagnosis of respiratory conditions (e.g. blood gas testing); monitoring of diabetic patients (e.g. blood glucose testing); monitoring of blood coagulation patients (e.g. INR testing); cardiac conditions (e.g. troponin testing), and; sepsis testing.

Similarly, the ninth objective of the research was to identify the major disadvantages of using POCT in hospital-based care. The most commonly cited issues in this regard were; increased cost compared to CLT; poor quality and/or inaccuracy of test result due to operator error; issues of connectivity to central patient record systems; significant resource required to sustain an appropriate quality management system, which is difficult to control due to the dispersed nature of POCT; staff training requires a substantial amount of time dedication, and; POCT will not give you the same accuracy as CLT, and can therefore cause duplication of tests already being carried out by the central laboratory.

As indicated at the outset, this research was designed with the intent of not only identifying problems with the adoption of POCT in hospital-based healthcare but also providing potential solutions to the issues impeding its further uptake. Importantly, the nature of the solutions need to be defined following a sound and complete understanding of the underlying problems. In this regard, by way of achieving the eleventh and final research objective, the following solutions are suggested as a means to overcome the issues identified and categorised within this thesis:

- POCT use should be audited in a long-term evidence gathering exercise in order to provide verification of both the clinical and economic benefits that may be available through its utilisation. As such, the increased cost associated with POCT can be justified by the improvements in patient care and cost-effectiveness could be better judged. This would overcome much scepticism with regard to POCT that has been identified as existing;
- POCT results should be better connected to the patient record systems, without the use of multiple middleware interface systems. Appropriate regional/national standards should be implemented for POCT data in a way that makes it as compatible with CLT data as possible;
- Training processes should be improved, to include re-training and periodic competency tests of all users to ensure familiarity with operational aspects of devices. The effectiveness of POCT devices to provide high quality results is largely dependent on the competence of the operator and, as such, training is a vital component for minimising the risk of poor quality and/or inaccurate results, which can result in patient morbidity or mortality;
- Costs of both POCT devices and implementation should be reduced and their uptake in healthcare facilities targeted to deliver specified outcomes. This can be achieved through a central POCT funding source. In a time of shrinking healthcare budgets across the globe, any increase in cost is difficult to justify when evidence of clinical benefit is currently limited;
- A regional consensus and/or strategy on POCT procurement should be agreed. A defined (capability led) procurement strategy for POCT would lead to increased efficiency in their use. POCT devices are generally a form of mobile technology and hence can be utilised within different locations if proper planning is in place to allow for this without any loss of quality;
- Central Laboratory Service support for POCT and a plan for sufficient aftercare provision should be implemented, with a dedicated team provided to manage quality assurance processes. A team of analytically trained professionals, who are familiar with the regulatory requirements of diagnostic testing, would ensure that errors are kept to a minimum and, as such, this arrangement would increase operator confidence in the system overall;
- Fit for purpose quality assurance programmes should be improved and audited. Auditing the quality systems in place will overcome both clinician and laboratory anxiety about testing quality; and

- All areas involved in POCT operation must collaborate more closely to ensure the effective utilisation of POCT. Clear lines of clinical governance along with roles and responsibilities must be defined.

8.2 Recommendations for Further Work

While the merits and contribution to knowledge of this body of research have been described, above, its limitations are also recognised. Resource constraints have allowed for only representation clinical groups from the UK and US healthcare systems to participate. As such, the findings of this research could be validated on a larger scale, incorporating larger samples of each of the respective healthcare professionals. Furthermore, while the UK and US health systems were compared herein, other examples of the specifics of national healthcare provision in Europe, the Americas and Asia could be added to provide a more global dimension. Finally, while this body of research has focused on POCT use within the secondary care (hospital) system, additional research could be conducted to investigate the barriers to adoption of POCT within primary care and how these relate to the situation found here within the hospital-based care environment.

Appendix A

UK Study Questionnaire

Study: A survey of clinical opinion on the utility of point-of-care testing (POCT) devices.

Note: Participants are encouraged to answer only those questions which they feel are relevant. Responses to interview questions should be made today.

Questions 1-4 will be used to qualify the responses in respect to clinical speciality, user experience and category of device.

1. Please state your area of clinical practice/specialty.

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2. How would you rate your own expertise in the practical use of a POCT device? *(Please tick the appropriate box below)*

Not yet completed training.	Use under supervision.	Basic level capability – Unsupervised use.	Competent – Unsupervised use and maintenance.	Highly proficient- Recognised trainer.

3. Are any point-of-care testing devices used to diagnose patients in your area of clinical practice/specialism? *(Please tick the appropriate box below) If yes continue to Question 4, if no please go to Question 7.*

Yes	No

4. Please tick the type(s) of POCT device used in your area of clinical practice/specialism.

Blood Lactate Analyser	
Cardiac Marker Analyser	
Urine Pregnancy Test Kit	
Coagulation Analyser	
Urea, Electrolytes & Creatinine Test	
CRP Analyser	
Blood Glucose Analyser	

Blood Gas Analyser	
Drugs of Abuse Screening	
Other (*please specify*)	

Questions 5 and 6 address experience of POCT usage within a clinical environment.

5. Approximately, what percentage of diagnostic tests in your area of clinical practice/specialism is performed using POCT?

	%

6. **(a)** Have you experienced any levels of patient mistrust of POCT devices*? (Please tick all of the appropriate boxes below)*

I have never experienced any level of patient mistrust towards a POCT device.	**Patient queries the capability of a POCT device.**	**Patient requests evidence of the capability of a POCT device.**	**Patient refuses test to be carried out with a POCT device.**

If you have experienced a situation where a patient has refused a test to be carried out using a POCT device then please continue to part (b). Otherwise, please go to Question 7.

(b) In your experience, approximately how often does a patient refuse a test to be carried out using a POCT device? *(Please tick the appropriate box below)*

Almost never (<1%)	**Rarely (1%-5%)**	**Not very often (6%-10%)**	**Significantly often (>10%)**

Questions 7 to 21 seek to attain a semi-quantitative assessment of the practical utility of POCT devices.

- **Questions preferably should be answered in relation to the type(s) of device used in your area of clinical practice/specialism, as selected in Question 4.**
- **POCT refers to Point-of-Care Testing.**
- **CLT refers to traditional Central Laboratory Testing.**

Economic Issues

7. **(a)** Do you agree that the cost per test of POCT is higher than CLT? *(Please tick the appropriate box below)*

Yes	No

(b) ***(i)*** On a scale of 1 to 10, to what extent do you agree or disagree that, POCT provides longer term economic benefits e.g. reduced hospital stay, reduced outpatient appointments etc.

Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

If you rated your level of agreement as 5 or below then please continue to part (b)(ii). Otherwise, please go to part (c).

(ii) In your opinion, why are the longer term economic benefits potentially available through the use of POCT not being realised fully?

(c) Would you agree that the use of a POCT system is cost-effective? *(Please tick the appropriate box below).*

Yes	No

8. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that procurement, reimbursement and budgeting in your institution sufficiently accommodate the interdepartmental nature of POCT, especially where it is a shared resource?

Strongly Disagree	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Strongly Agree**

If you rated your level of agreement as 5 or below then please continue to part (b). Otherwise, please go to Question 9.

(b) Does this lack of specific accommodation make it difficult to utilise POCT to its full potential in your institution? *(Please tick the appropriate box below)*

Yes	**No**

9. Please rate the following issues in terms of relevance within your clinical environment, using the table below. *(Please tick the appropriate box below for each issue)*

Issue	**Not relevant**	**Rarely relevant**	**Sometimes relevant**	**Fairly relevant**	**Very relevant**
Difficult to justify the use of POCT devices as the simple cost per test of POCT is higher than traditional CLT.					
Difficult to justify the implementation of a POCT system as the true cost-effectiveness of such a system is difficult to gauge and cost comparison studies against traditional central laboratory testing methods are complex.					
Difficult to justify the implementation of a POCT system as the initial costs of implementing such a system are high.					
Issues with regards to budget contributions towards POCT due to the allocation of separate budgets for separate departments which is not appropriate for interdepartmental nature of POCT.					

Difficulty in obtaining reimbursement for POCT. (i.e. who pays for the test?)					

Quality Assurance & Regulatory Issues

10. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that the dispersion of POCT devices through the healthcare system gives rise to opportunities for untrained or non-competent staff to use the devices, leading to an increased disregard of certain quality assurance steps and procedures, including quality control?

Strongly Disagree	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Strongly Agree**

If you rated your level of agreement as 6 or above then please continue to part (b). Otherwise, please go to Question 11.

(b) Does the increased disregard of certain quality assurance steps and procedures that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	**No**

11. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that regulations for analytical testing accreditation for POCT are overly complex?

Strongly Disagree	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Strongly Agree**

If you rated your level of agreement as 6 or above then please continue to part (b). Otherwise, please go to Question 12.

(b) Does the burden imposed by such requirements that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

12. **(a)** On a scale of 1 to 10, how much operator training and support on regulatory compliance for POCT are provided by your central laboratory?

Very Little	1	2	3	4	5	6	7	8	9	10	Very Much

If you rated this level of training and support as 5 or below then please continue to part (b). Otherwise, please go to Question 13.

(b) Does this lack of training and support that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

13. Please rate the following issues in terms of relevance within your clinical environment, using the table below. *(Please tick the appropriate box below for each issue)*

Issue	Not relevant	Rarely relevant	Sometimes relevant	Fairly relevant	Very relevant
Errors due to incorrect quality assurance steps or procedures by untrained or non-competent staff operating the POCT devices.					
Complex accreditation regulations written for traditional laboratory instrumentation are blindly applied to modern POCT devices, causing issues for non-laboratory operators.					

Issues with maintaining compliance with regulatory requirements due to a number of changes in the accreditation regulations.					
Issues with maintaining compliance with regulatory requirements due to the dispersed nature of POCT devices making them difficult to control.					
A lack of development of POCT devices, caused by product approval hurdles discouraging economic investment in their development.					

Device Performance & Data Management Issues

14. **(a)** On a scale of 1 to 10, how do you rate the level of analytical performance (i.e. specificity,

sensitivity & precision) of a POCT device in comparison to a traditional CLT instrument?

Very Low	1	2	3	4	5	6	7	8	9	10	Very High

If you rated the level of analytical performance as 5 or below then please continue to part (b). Otherwise, please go to Question 15.

(b) Does the reduced analytical performance that you have indicated in part (a) make it more difficult to make a timely and reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

15. **(a)** On a scale of 1 to 10, how do you rate the connectivity (i.e. to the central healthcare and patient record systems) and data management of a POCT system in comparison to a traditional CLT instrument?

Very Poor	1	2	3	4	5	6	7	8	9	10	Very Good

If you rated the connectivity and data management as 5 or below then please continue to part (b). Otherwise, please go to Question 16.

(b) Does the poor connectivity and data management that you have indicated in part (a) make it more difficult to make a timely & reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

16. **(a)** On a scale of 1 to 10, how do you rate the difficulty of performing tests using POCT devices compared to that of a CLT system?

Very Easy	1	2	3	4	5	6	7	8	9	10	Very Difficult

If you rated the difficulty of performing tests using POCT devices as 6 or above then please continue to part (b). Otherwise, please go to Question 17.

(b) ***(i)*** Does the increased difficulty that you have indicated in part (a) make it more difficult to attain a timely & reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

(ii) In your opinion, how could the usability of POCT devices be improved?

17. Please rate the following issues in terms of relevance within the clinical environment, using the table below. *(Please tick the appropriate box below for each issue)*

Issue	Not relevant	Rarely relevant	Sometimes relevant	Fairly relevant	Very relevant
POCT devices producing reduced analytical performance in comparison to traditional centralised testing.					
POCT system poorly connected to main healthcare and patient record systems, causing data management issues.					
POCT device operators encountering difficulties with their use.					

Staff & Operational Issues

18. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that POCT significantly increases the workload of front line clinical staff (i.e. device operators)?

Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

If you rated your level of agreement as 6 or above then please continue to part (b). Otherwise, please go to Question 19.

(b) Does the increased workload that you have indicated in part (a) reduce staff satisfaction levels in comparison to when utilising CLT? *(Please tick the appropriate box below)*

Yes	No

19. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that the central laboratory are reluctant to allow the control of testing to be passed on?

Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

If you rated your level of agreement as 6 or above then please continue to part (b). Otherwise, please go to Question 20.

(b) Does the resistance that you have indicated in part (a) act as an impediment to the more widespread adoption of POCT within the clinical environment? *(Please tick the appropriate box below)*

Yes	No

20. **(a)** On a scale of 1 to 10, to what extent do you agree or disagree that the clinical care pathway and role of the central laboratory have been altered sufficiently to incorporate the use of POCT?

Strongly Disagree	1	2	3	4	5	6	7	8	9	10	Strongly Agree

If you rated your level of agreement as 5 or below then please continue to part (b). Otherwise, please go to Question 21.

(b) Does this poor integration of POCT that you have indicated in part (a) make it more difficult to attain a timely and reliable diagnosis in comparison to utilising CLT? *(Please tick the appropriate box below)*

Yes	No

21. Please rate the following issues in terms of relevance within your clinical environment, using the table below. *(Please tick the appropriate box below for each issue)*

Issue	Not relevant	Rarely relevant	Sometimes relevant	Fairly relevant	Very relevant
Reduced staff satisfaction levels and increased friction between staff groups.					
The resistance of central laboratory to allow the control of testing to be passed on acts as an impediment to the more widespread uptake of POCT.					
Inappropriate use of POCT (i.e. over-use and reliance on test results, undermining clinical expertise).					
The full benefits of POCT are not being realised as significant alterations to clinical care pathways and the central laboratory are required.					
POCT system does not run efficiently as an interdepartmental management structure is required with clear clinical governance for POCT.					
Reluctance to change within health services and a lack of evidence justifying POCT makes it hard to justify the implementation of such a system.					

Questions 22-26 seek to gain opinion on the general use and adoption of POCT.

22. What do you think are the main advantages of using POCT in comparison to CLT?

23. What do you think are the main disadvantages of using POCT in comparison to CLT?

24. Which diseases and/or conditions do you feel benefit the most from the use of POCT for more effective diagnosis and/or monitoring?

25. What do you suggest could be possible solutions to overcoming any of the real or perceived barriers to the adoption of POCT technologies?

26. Please rank the following categories of issues in order of current impact on POCT adoption, using the table below (from 1 to 4 where 1 is most current impact and 4 is least current impact).

a. **Economic Issues**

(i.e. higher cost/test ratio, difficult to gauge cost-effectiveness, high initial implementation costs, inappropriate budget allocations, reimbursement hurdles)

b. **Quality Assurance & Regulatory Issues**

(i.e. device operation by untrained/non-competent staff, complex regulatory requirements, product qualification hurdles)

c. **Device Performance & Data Management Issues**

(i.e. reduced analytical performance in comparison to centralised testing, connectivity & data management issues, poor usability of devices)

d. **Staff & Operational Issues**

(i.e. reduced staff satisfaction levels and friction between staff groups, reluctance of central lab to allow testing to be passed on, significant alterations to clinical care pathways and the central lab are required, an interdepartmental management structure with clear clinical governance for POCT is required, a lack of evidence justifying POCT and a reluctance to change within the healthcare sector)

Most Current Impact

Rank	**1**	**2**	**3**	**4**
Category (letter)				

Least Current Impact

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE AND CONTRIBUTING TO THE ASSOCIATED RESEARCH PROJECT.

– YOUR CONTRIBUTION IS GREATLY APPRECIATED.

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